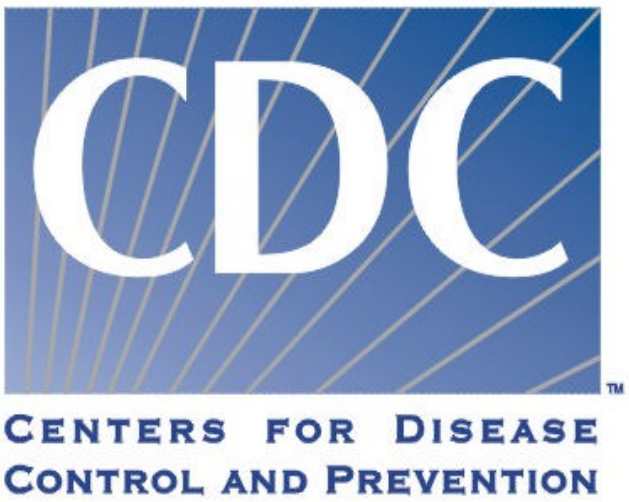
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV, Hepatitis, STD and TB Prevention
[proposed]
Division of Tuberculosis Elimination



Advisory Council for the Elimination of Tuberculosis
March 20-21, 2007
Atlanta, Georgia

Record of the Proceedings

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List of Participants

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Dr. William Burman
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Dr. Richard Fluck
Mr. Shannon Jones III
Mr. Joseph Kinney
Dr. Ana Lopez-De Fede
Dr. Masahiro Narita
Dr. Barbara Seaworth
Ms. Sirlura Taylor

***Ex-Officio* and Liaison Members**

Dr. William Baine (AHRQ)
Dr. Amy Bloom (USAID)
Dr. Jane Carter (IUATLD)
Dr. James Cheek (IHS)
Dr. Linda Danko (VA)
Dr. Richard Ehrenberg (NIOSH)
Dr. Patricio Escalante (ACCP)
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Dr. Michael Leonard (IDSA)
Dr. David Mills (APHL)
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William Mac Kenzie
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Joseph Scavotto
Margie Scott-Cseh
Phillip Talboy
Victor Tomlinson
Andrew Vernon
Elsa Villarino
Wanda Walton
Cornelia White
Holly Wilson
Carla Winston

Guest Presenters and Members of the Public

Deliana Garcia
(Migrant Clinicians Network)
Kenneth Johnson (Georgia Department of Human Resources)
Kathleen Moser (San Diego County Health and Human Services Agency)
Paul Poppe (McKing Consulting)
Carol Pozsik (National Tuberculosis Controllers Association)
Rachel Royce (RTI International)

John Seggerson (National Coalition for the Elimination of Tuberculosis)

Vivian Watson (CDC National Prevention Information Network)

Claire Wingfield (Treatment Action Group)

ATTACHMENT 2

Acronyms Used In This Report

AAs	—	African Americans
ACET	—	Advisory Council for the Elimination of Tuberculosis
ALA	—	American Lung Association
APHL	—	Association of Public Health Laboratories
BBCMP	—	Binational Bridge Case Management Program
BHC	—	Border Health Commission
BHW	—	Binational Health Week
BSC	—	Board of Scientific Counselors
CBOs	—	Community-Based Organizations
CBP	—	U.S. Customs and Border Protection
CCID	—	Coordinating Center for Infectious Diseases
CDC	—	Centers for Disease Control and Prevention
CDPH	—	Chicago Department of Public Health
CETBA	—	Controlling and Eliminating TB in AA Communities Advisory Board
CHAC	—	CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
CHCs	—	Community Health Centers
CMS	—	Centers for Medicare and Medicaid Services
CSG	—	Core Science Group
DGMQ	—	Division of Global Migration and Quarantine
DIHS	—	Division of Immigration Health Services
DOT	—	Directly Observed Therapy
DST	—	Drug Susceptibility Testing
DTBE	—	Division of Tuberculosis Elimination
FACs	—	Federal Advisory Committees
FBOs	—	Faith-Based Organizations
FBWG	—	Foreign-Born Workgroup
FTBTF	—	Federal TB Task Force
GDHR	—	Georgia Department of Human Resources
GIS	—	Geographic Information System
HALT TB	—	Hear, Act, Learn, Treat TB
HHS	—	Department of Health and Human Services
HRSA	—	Health Resources and Services Administration
ICE	—	U.S. Immigration and Customs Enforcement
IFS	—	Institute for Families in Society
IOM	—	Institute of Medicine
IUATLD	—	International Union Against TB and Lung Disease
LTBI	—	Latent TB Infection
MCN	—	Migrant Clinicians Network
MDR-TB	—	Multi-Drug Resistant TB
MEG	—	Mandatory Eligibility Group
MMWR	—	*Morbidity and Mortality Weekly Report*

MRC	—	Medical Research Council
NCET	—	National Coalition for the Elimination of Tuberculosis
NCHHSTP	—	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention [proposed]
NEDSS	—	National Electronic Disease Surveillance System
NIH	—	National Institutes of Health
NMA	—	National Medical Association
NTCA	—	National Tuberculosis Controllers Association
OGAC	—	Office of the Global AIDS Coordinator
OHRP	—	Office of Human Research Protection
PAHO	—	Pan American Health Organization
PLWHA	—	Persons Living With HIV/AIDS
QFT	—	QuantiFERON-TB
R&D	—	Research and Development
RTMCCs	—	Regional Training and Medical Consultation Centers
RVCT	—	Reported Verified Case of TB
SCDHEC	—	South Carolina Department of Health and Environmental Control
SE-8	—	Eight Southeastern States
SES	—	Socioeconomic Status
SSI	—	Supplemental Security Income
STAR	—	Semiannual TBESC Advisory Review
TAG	—	Treatment Action Group
TBESC	—	TB Epidemiologic Studies Consortium
TBTC	—	TB Trials Consortium
TIMS	—	Tuberculosis Information Management System
TIs	—	Technical Instructions
TST	—	Tuberculin Skin Test
USAID	—	U.S. Agency for International Development
USG	—	U.S. Government
WHO	—	World Health Organization
XDR-TB	—	Extensively Drug-Resistant TB

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
March 20-21, 2007
Atlanta, Georgia

Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on March 20-21, 2007 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

Opening Session

Dr. Kenneth Castro, the Acting ACET Executive Secretary, called the meeting to order at 8:30 a.m. on March 20, 2007. He announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest identified by the CDC Committee Management Office and recuse themselves from voting or participating in these discussions.

Dr. Michael Fleenor, the ACET Chair, welcomed the participants to the meeting and opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Update by the Director of the National Center for HIV/AIDS, Hepatitis, STD and TB Prevention (NCHHSTP) [proposed]

Dr. Kevin Fenton covered the following areas in his update. Dr. Julie Gerberding, the CDC Director, participated in a Congressional briefing on March 7, 2007 to inform Congress about extensively drug-resistant TB (XDR-TB). On March 21, 2007, Dr. Gerberding will testify before the Africa and Global Health Subcommittee of the House Foreign Affairs Committee. NCHHSTP hopes that Dr. Gerberding's Congressional briefings will result in increased TB funding.

In terms of CDC's TB budget, Dr. Fenton announced that the joint budget resolution passed for FY'07 resulted in flat funding. The President's FY'08 budget request for TB is $136.8 million.

Dr. Fenton described key changes in NCHHSTP's senior leadership. Dr. Nickolas DeLuca is serving as the Acting Associate Director for Health Disparities after Dr. Hazel Dean was appointed as the Acting Deputy Director of NCHHSTP. Ms. Susan DeLisle is serving as the Acting Associate Director for Program Integration.

Dr. Fenton summarized NCHHSTP's ongoing efforts to integrate HIV, viral hepatitis, STD and TB prevention programs. NCHHSTP has defined "program integration" as organizing and blending interrelated health issues, separate activities and services to maximize public health impact through new and established linkages to facilitate the delivery of services. NCHHSTP's definition of "integration" focuses on integrated services for the client regardless of the agency structure.

Integrated services may include HIV, STD, and hepatitis B and C counseling and testing; partner services and referrals to additional prevention or care; and hepatitis A and B immunization. NCHHSTP will ensure that integration is focused at the field or client level because the interface between the system and consumer occurs at these levels.

NCHHSTP established several short-term goals for the new integration initiative. Implementation of new adult hepatitis B vaccination guidelines in STD and HIV evaluation and care settings will be supported. Strategies will be developed to strengthen partnerships with governmental agencies and community-based organizations (CBOs). Collaborations will be built across NCHHSTP's HIV, STD and viral hepatitis prevention and surveillance programs.

NCHHSTP also identified several priority activities to integrate the programs. Quarterly meetings will be held with program consultants. A methodology will be established to facilitate "reverse" site visits and promote an integrated approach to program reviews. Instead of CDC staff making site visits to the field, state or field staff will attend program review meetings at CDC under the reverse site visit process. Coordination and communication to grantees will be improved on Procurement and Grants Office issues.

A web-based NCHHSTP Intranet and Internet presence will be developed for program consultants to share and communicate integration best practices. Templates and standards will be designed for joint trip reports. Deployments of program consultants and field staff will be maximized during public health emergencies.

Dr. Fenton was pleased to report on the success of site visits NCHHSTP senior staff and colleagues in the Division of Tuberculosis Elimination (DTBE) made in February 2007. CDC met with state and local public health officials, CBO staff and other stakeholders in Los

Angeles, Richmond, Sacramento and San Francisco, California. CDC's site visits included meetings with three TB control program directors in the state: Dr. Masae Kawamura in San Francisco; Dr. Annette Nita in Los Angeles County; and Dr. Sarah Royce in the state of California. CDC examined integrated and client-centered programs during the California site visits.

Dr. Fenton announced that the first "TB Awareness Walk" would be held on March 24, 2007 beginning at 9:00 a.m. in Grant Park in Atlanta, Georgia. NCHHSTP is sponsoring the event in partnership with the National Tuberculosis Controllers Association (NTCA), Fulton County Health Department, Georgia Department of Public Health, American Lung Association (ALA), Watsonian Society and local businesses. At this time, >400 participants have registered for the event. NCHHSTP and its partners hope that the first TB Awareness Walk will be institutionalized as an annual event to continue to build bridges with the community.

Dr. Kenneth Castro, ACET's Acting Executive Secretary and Director of DTBE, provided additional details about the TB budget in response to ACET's questions. His position was that DTBE should request and would need a budget of $528 million to implement all of the recommendations in the 2000 Institute of Medicine (IOM) report on TB elimination in the United States. However, this budget would not include the current level of funding that is needed to fight XDR-TB.

Despite the constraints in the current TB budget, Dr. Castro was pleased to announce that the Office of the Global AIDS Coordinator (OGAC) targeted additional funding in the amount of $120 million to fight TB/HIV co-infection. The source of these dollars was new funding of $350 million for activities under the President's Emergency Plan for AIDS Relief.

Dr. Castro also informed ACET that the impact of Dr. Gerberding's recent Congressional briefings on increased funding to address domestic TB problems is unknown at this time. He encouraged ACET to continue to advocate for additional domestic funding for TB.

Drs. Burman, Fenton and Fleenor provided an update on another issue of importance to ACET and NCHHSTP. ACET previously raised concerns about the Coordinating Center for Infectious Diseases (CCID) establishing a new Board of Scientific Counselors (BSC) due to the possibility of TB being "lost" or overwhelmed by other infectious disease issues. However, Drs. Burman, Fenton and Fleenor attended the last BSC meeting on March 15-16, 2007 and were pleased to report that the meeting was positive and energizing.

TB was extensively discussed during the meeting after several participants emphasized the critical need to address new technologies for surveillance of multi-drug resistant TB (MDR-TB), new diagnostic technologies and XDR-TB. The BSC meeting was also successful in terms of providing a forum for CCID stakeholders and staff to share perspectives from both scientific and programmatic perspectives. Minutes of the March 2007 BSC meeting would

be available over the next six to eight weeks. Dr. Fleenor was particularly pleased with the direction of the BSC at this point.

Several ACET members advised NCHHSTP to broaden the list of invited participants to the upcoming TB Awareness Walk beyond CBOs. For example, letters of invitation should be sent to churches and attendees of CDC's May 2006 "Stop Tuberculosis in the African American Community Summit for Success."

Overview of Medicaid Reimbursement for TB Services

Ms. Carol Pozsik, Executive Director of NTCA, reported on issues and challenges that TB control programs face in attempting to obtain reimbursement from Medicaid for TB services. TB control programs previously relied on state or local funds for program operation, but began receiving funds from federal cooperative agreements in 1982 to cover staff and travel expenses. State and local agencies still provide support for patient diagnosis, treatment, prevention and surveillance, but state and federal funding for TB sources has been declining over the past several years.

Many TB programs still use state and local funds to provide free outpatient services to patients because TB is a communicable disease. TB patients who are not required to pay for clinic visits, medications or other services will be more likely to seek and complete treatment. Most TB patients are low-income males who do not qualify for traditional Medicaid services. Females are more likely to be eligible for Medicaid due to their enrollment in maternity, family planning, or Women, Infant and Children's programs.

Some Medicaid programs cover limited TB services if the client is already eligible and a billing system has been established. Most TB programs do not collect income data unless efforts are made to bill traditional Medicaid programs. Some TB programs provide funding for inpatient hospitalization for complicated diagnosis and treatment services that are beyond the scope of regular outpatient services. CDC cooperative agreement funds pay for staff and administrative services, but do not pay for drugs, x-rays and other direct treatment services.

Medicaid is a federal-state matching entitlement program under the Social Security Act. Medicaid provides medical assistance for certain persons and families with low incomes and resources. Medicaid is the largest program that provides medical and health-related services to America's poorest citizens.

The federal government established broad guidelines for states to implement Medicaid. Each state must (1) establish its individual eligibility standards; (2) determine the type, amount, duration and scope of services covered; (3) establish rates of payment for services;

and (4) administer its individual program. Due to these broad federal guidelines, Medicaid programs vary among states.

Medicaid does not provide assistance for all poor persons even under the broadest provision of the federal statute. Medicaid qualification is determined by enrollment in a mandatory eligibility group (MEG) with low income being only one criterion of an established eligibility threshold. MEGs include recipients of Aid to Families with Dependent Children; aged, blind or disabled persons who receive Supplemental Security Income (SSI) and qualify in states with more restrictive eligibility requirements; and pregnant women with a family income <133% of the federal poverty level. Each state determines these limits within federal guidelines. Overall, states have broad discretion in determining groups to cover under Medicaid.

Examples of state options include non-coverage of pregnant women and infants up to 1 year of age under mandatory rules; eligibility to persons receiving care under home or community-based waivers; and the provision of TB-related ambulatory services and drugs only for TB-infected persons who would be financially eligible for Medicaid at the SSI income level.

The Medicaid Act was amended in 1993 to allow states to extend eligibility to TB-infected persons, but state income eligibility criteria must be met. The amendment covers TB infection, disease and suspected cases, but coverage is limited to the treatment period. The amendment does not qualify clients for other Medicaid services.

The federal-state match is the amount that a federal agency will match state costs for services. The federal-state match is determined by a federal committee, but varies among states. Medicaid policies for eligibility are complex and considerably differ among states. For example, Medicaid-eligible persons in one state may not be eligible in another state. Services within a state may change from year to year.

States have the option to cover certain TB services under Medicaid, such as outpatient clinic visits, medications, directly observed therapy (DOT) visits, diagnostic and follow-up x-rays, and laboratory tests. However, Medicaid cannot be used to pay for contact investigations or hospitalization.

Medicaid payment for services is a “vendor-type” system in which states and health departments directly pay providers. Providers must accept reimbursement as payment in full. States generally have broad discretion in implementing the reimbursement methodology and rate for services, but a federal limit has been imposed for an upper limit and specific restrictions. Some states impose nominal deductibles or co-payments from clients.

NTCA administered a survey to all 50 states in 2006-2007 to obtain information about use of the Medicaid TB option. The survey showed that only five states use the Medicaid TB

option: Arkansas, California, Maine, South Dakota and Wisconsin. The remaining states reported a variety of reasons for not using the Medicaid TB option. Some states cover the costs of drugs, clinic operations, other treatment and hospitalization. Some state Medicaid agencies do not have funds for the TB option. Some states reported that public health administration would not support the Medicaid TB option.

Some states found the establishment of the administrative process to be difficult and overly burdensome to the TB program due to minimal clerical staff to perform these functions. Some states had inadequate staff to bill Medicaid and all clients. Some states reported that the up-front federal-state match is too large because funds taken from state TB program dollars would cause deficits in funding for required services. Two states had no knowledge of the Medicaid TB option. Some states determined that the two-year period to apply the Medicaid TB option would be time consuming.

Some states had sufficient funding from Medicaid-eligible patients and adequate coverage of most clients by the Indian Health Service. Some states reported use of the Medicaid TB option, but not in all counties. Some states identified gaps in coverage in terms of drugs, hospitalization or no field DOT. Some states had expanded coverage for Medicaid-eligible persons. Some states had Medicaid reimbursement for laboratory and diagnostic tests, x-rays and private physician visits.

Some states reported large populations of undocumented immigrants who are ineligible for Medicaid programs. "Path to Citizenship" and Guest Relations" programs require five years of residence in the United States to become eligible for Medicaid even after obtaining U.S. citizenship. Refugees are only eligible for Medicaid for a period of six to nine months. Overall, TB programs with large populations of foreign-born persons bear a tremendous financial burden.

Ms. Pozsik concluded her overview by inviting ACET to obtain additional information about the Medicaid TB option from the 2000 IOM report on TB elimination in the United States and the web site of the Wisconsin TB program.

Several ACET members expressed concern about the tremendous gap in Medicaid funding. Many members noted that undocumented immigrants are ineligible for Medicaid services, but account for the majority of expensive MDR-/XDR-TB cases in the United States. The members also pointed out that Medicaid does not cover home infusion services, hospitalization or air ambulance transportation. A number of ACET members made suggestions to improve reimbursement for TB services through Medicaid.

- Education and technical assistance should be broadly provided at the local level on implementing the Medicaid TB option. Many local TB programs have been unsuccessful in billing Medicaid for TB services even in states that have this option. Local TB programs are typically unable to overcome the

enormous challenges, difficulties and complexities in using the Medicaid TB option.

- ACET should develop and distribute a packet of materials to states on options to maneuver through the Medicaid system. The dissemination of models and best practices could assist states in overcoming barriers to reimbursement for TB services through Medicaid. For example, undocumented immigrants are ineligible for Medicaid services, but the state of Alabama gives an "emergency pregnancy status" to pregnant immigrants. This approach allows pregnant immigrants in the state to qualify for Medicaid services and receive TB services under the Medicaid TB option.
- ACET should consider the possibility of issuing a formal statement in strong support of free TB care. Other infectious disease models should be gathered to support this effort. For example, the recent experience of Denver's STD clinic in charging a co-payment was tremendously unsuccessful and resulted in statistically significant decreases in diagnoses of HIV, gonorrhea and chlamydia.
- Best practices and models from the five states that are successfully using the Medicaid TB option should be compiled and widely distributed to other states. This approach would provide a framework for broader implementation of the Medicaid TB option.
- Documentation should be gathered and disseminated on the disproportionate hospital share associated with TB. These materials would serve as a key informational resource to Medicaid agencies.
- Federal agencies should identify funds to cover TB services between the time of identification of infectious MDR-TB cases and culture conversion.

Dr. Castro strongly supported the suggestion for ACET to issue a formal recommendation or statement regarding the removal of all financial barriers to TB care. He added that ACET's guidance could acknowledge both the public health and individual benefits of treating persons with TB by interrupting the chain of transmission.

DTBE Director's Report

Dr. Castro covered the following areas in his report. Dr. Castro announced that his brief departure from the ACET meeting was to participate in a pre-briefing conference call with Dr. Gerberding and high-level representatives from OGAC and the U.S. Agency for International Development (USAID). The conference call was in preparation of Dr. Gerberding's testimony on the following day before the Africa and Global Health Subcommittee of the House Foreign Affairs Committee.

On March 6-7, 2007, OGAC convened CDC, USAID, the World Health Organization (WHO), and representatives from other organizations funded by the Gates Foundation to discuss

innovative new diagnostics. The meeting was held to explore the possibility of accelerating the field testing and rollout of newer technologies in countries in most need of these tools.

Several developments occurred on XDR-TB following the December 2006 ACET meeting. Five senators requested a briefing on XDR-TB in March 2007. XDR-TB was a key discussion topic during the May 15-16, 2007 BSC meeting. CDC has been informed that the White House will request the establishment of an interagency team on XDR-TB.

Dr. Castro described several upcoming events related to World TB Day in 2007. WHO and the International Union Against TB and Lung Disease (IUATLD) established the theme of "TB anywhere is TB everywhere" for World TB Day. Three articles related to TB will be published in the March 23, 2007 edition of the *Morbidity and Mortality Weekly Report* (*MMWR*) on national TB morbidity based on provisional results; XDR-TB in the United States; and technical instructions for screening of immigrants and refugees. The first "TB Awareness Walk" will be held on March 24, 2007 in Grant Park in Atlanta, Georgia. The CDC web site contains a map that provides information on World TB Day activities that will be held in each state.

Dr. Castro reported on TB data that were recently collected and analyzed. Provisional data will be published in the *MMWR* on the national TB case rate in 2005-2006 after the embargo is lifted. The data showed a 3.2% decline between the incidence of 4.8/100,000 in 2005 and 4.6/100,000 in 2006. Data on TB trends in the United States from 1993-2006 showed a statistically significant slowing in the rate of decline beginning in 2000. The annual percent change in the TB rate was 7.3% in 2000 compared to 3.8% in 2006. These data demonstrate that TB elimination will only occur after several generations unless the pace is accelerated at this time.

Preliminary data on the number of persons with TB and the rate of TB by origin of birth and year in the United States from 1993-2006 showed a dramatic gap between U.S-born and foreign-born TB cases per 100,000 population. Data collected on MDR-TB in 2004-2005 showed that 1.2% of all culture-positive cases met the case definition for MDR-TB. Foreign-born cases represented 76% of MDR-TB in 2004 and 81.5% in 2005.

The upcoming *MMWR* article on characteristics of XDR-TB cases in 1993-1999 versus 2000-2006 will report that 49 persons captured in the national surveillance registry met the case definition for XDR-TB over these two time periods. Foreign-born cases represented 40.6% of XDR-TB in 1993-1999 and 76.5% in 2000-2006. The *MMWR* article will also report the HIV status of these cases.

Dr. Castro reported that CDC released an announcement on March 14, 2007 to fill the position of DTBE's Field Services and Evaluation Branch Chief. The announcement will close on March 27, 2007. Both CDC and non-CDC candidates with expertise in the medical or science field are welcome to apply.

Dr. Castro informed ACET that CDC will no longer support the National Electronic Disease Surveillance System (NEDSS) program area module (PAM) platform. The TB PAM was scheduled to be included in NEDSS, but CDC was dissatisfied with the pilot test in Ohio. CDC will continue to support the base system and standards for NEDSS and the Public Health Information Network. DTBE will take several actions to ensure that TB surveillance is not impaired by this new development. As a short-term solution, DTBE will continue to support the Tuberculosis Information Management System (TIMS) and its import utility system through the national TB surveillance system.

DTBE will collaborate with the National Center for Public Health Informatics in a number of efforts. Enhanced NEDSS TB message development will be accelerated for reporting areas that are already developing systems. The possibility will be explored of adding the TB PAM to the existing NEDSS base system for reporting areas that need CDC's data entry tool. A survey will be administered to determine the availability of TB software applications developed by private vendors. DTBE will convene a conference call and host a web-based seminar on March 23, 2007 with NTCA, TB program directors and TB surveillance coordinators as an initial step in developing an action plan.

Dr. Castro conveyed that DTBE is continuing its efforts to address challenges in TB programs resulting from reductions in TB control program funds, decreased efficiency and accountability, a decline in cases, an increase in the complexity of cases, and the loss of expertise. CDC's TB cooperative agreements funds decreased after adjusting for the consumer price index. In response to the reduction in TB dollars since FY'01, DTBE created a formula to redistribute TB cooperative agreement funds.

The first phase of the redistribution plan was implemented in FY'05 with 20% of funds being redistributed. The second phase of the redistribution plan will be implemented in FY'08 with 35% of funds to be redistributed. A CDC/NTCA workgroup is continuing its discussions on adjusting the formula based on XDR-TB and other new developments that occurred after 2005. CDC will continue its strategic planning activities to modify future policies.

Dr. Castro reported that the Mycobacteriology Laboratory Branch will host a course in the summer of 2007. The course is structured for no more than 16 participants, but >30 persons applied. However, the laboratory course will be repeated based on successful evaluation. The course will be held in CDC's new training laboratories and classroom facility.

Dr. Castro was pleased to announce that DTBE will most likely receive one-time funding of ~$2 million in FY'07 from CDC's emerging infections funds. DTBE will use the additional funds to enhance laboratory capacity to pursue all MDR-/XDR-TB cases in the United States, support active outbreak response, and implement the BSC's recommendations. Dr. Castro confirmed that he noted Dr. Flood's suggestion for DTBE to collect and review national data on the infectious period of XDR-TB cases.

Update on the Federal TB Task Force (FTBTF)

Dr. Philip LoBue, of DTBE, described FTBTF's ongoing efforts to respond to XDR-TB. FTBTF was established in 1991 in response to the resurgence of TB and the increase in MDR-TB. FTBTF is represented by multiple federal agencies with shared responsibility for TB control and prevention in the United States, including program activities, research, services, and regulations on diagnostics and drugs. FTBTF is chaired by CDC.

In 1992, FTBTF developed the "National Action Plan to Combat MDR-TB." In 2000-2006, FTBTF implemented the U.S. government's (USG) response to the IOM report on TB elimination in the United States. In the fall of 2006, FTBTF initiated dialogue on USG's potential response to XDR-TB and held conference calls with OGAC to discuss this issue in more detail.

FTBTF agreed to form workgroups to develop USG's XDR-TB action plan with the following areas of focus: surveillance, epidemiology and outbreak investigations, laboratory capacity, infection control, clinical and programmatic issues, research, communication and education, partnerships and cost analysis. The workgroups were charged with using the 1992 "National Action Plan to Combat MDR-TB" as a model to develop the XDR-TB action plan and covering both domestic and international issues.

The workgroups were also given a format for the action plan. Each section would describe problems that must be addressed. Objectives that need to be achieved to address each problem would be listed. Action steps that must be implemented to achieve each objective would be described. Lead USG agencies, partners and additional resources would be identified for each action step. At this time, seven of the eight sections of the action plan have been submitted.

A contractor is now compiling the sections into a uniform document and expects to complete this task by March 31, 2007. FTBTF expects to complete its review of the entire document during a meeting on May 11, 2007 at the National Institutes of Health (NIH). Following the meeting, FTBTF will share the document with ACET, NTCA, the National Coalition for the Elimination of Tuberculosis (NCET), the Association of Public Health Laboratories (APHL), and the American Thoracic Society for review and comment.

To obtain broader input, FTBTF will discuss the possibility of asking ACET liaison members to distribute the XDR-TB action plan to their respective memberships. FTBTF expects to complete its revision of the action plan by May 31, 2007 based on input by non-federal partners and then submit the revised version of the document for clearance by HHS, OGAC and USAID.

Dr. LoBue concluded his update by informing ACET of recent developments regarding XDR-TB. During a briefing on March 7, 2007, the White House announced its plans to

convene an interagency team to address XDR-TB. FTBTF is considering strategies to integrate and share its action plan with the White House team. FTBTF's future actions will be determined by direction and guidance from the White House team.

ACET was pleased that USG is now taking more aggressive infection control precautions at both domestic and international levels. Several members made suggestions for FTBTF to consider in its ongoing efforts to finalize and distribute the XDR-TB action plan.

- FTBTF's action plan should acknowledge that difficult public health decisions will need to be made regarding XDR-TB. For example, strong political will is necessary for states to have control over XDR-TB cases, take appropriate infection control activities and manage untreatable patients. States should be given authority to ensure that private providers do not manage patients with XDR-TB due to the specialized expertise needed for this disease.
- FTBTF should closely coordinate and collaborate with the Association of Professionals of Infection Control and Epidemiology, Infectious Disease Society of America, Society for Healthcare Epidemiology of America, and other external partners in the infection control community in further development of the action plan. This approach will assist in the successful implementation of the action plan in areas with no or limited expertise and capacity in TB.
- ACET should release a scientific statement in conjunction with the release of the action plan. ACET's statement should emphasize the public health impact of XDR-TB to educate private providers and the public health community about the long chronic infectious period of XDR-TB, implications for long-term infection control, and the impact of treatment in clinical settings.
- FTBTF's action plan should raise the possibility of revisiting previous strategies that were implemented for long-term isolation of infectious patients.
- FTBTF should design the action plan as a resource to learn from and correct public health errors that were made in the management and treatment of MDR-TB. For example, solid data on the identification or treatment of contacts, release of MDR-TB cases into the community, and refusal of therapy are not obtained from MDR-TB patients who are managed in the home from the beginning of case identification.

Dr. Castro raised the possibility of linking to existing infection control efforts to address and leverage funding for emerging XDR-TB cases. For example, states that have received federal dollars to develop and implement pandemic influenza preparedness plans could use a portion of these resources to focus on XDR-TB.

Update on Global TB Research

Ms. Claire Wingfield, of the Treatment Action Group (TAG), reported that TAG was established in January 1992 and is the first and only AIDS organization solely dedicated to advocating for larger and more efficient public and private research efforts to find a cure for AIDS. TAG's TB/HIV project is supported by a Gates Foundation grant and is designed to combat TB/HIV co-infection through community-based advocacy, education, and mobilization efforts with AIDS advocates in developed and developing countries.

A review of the history of TB research shows that the 1940s and 1950s served as the height of TB drug discovery. TB research and development (R&D) stalled due to the tremendous decline in global TB disease between the 1940s and 1980, but TB made a dramatic comeback with the HIV pandemic.

TAG published the second edition of *Tuberculosis Research and Development: A Critical Analysis* in October 2006 to highlight gaps in spending and areas of scientific study in TB R&D. The report is targeted to policymakers, researchers and advocates. Sources of funding data and other information in the report include original donors, key stakeholders through interviews, public and private-sector organizations, and recipients and representatives of funding sources through self-reports. TAG received responses from 80 of 100 institutions that were asked to submit information.

Ms. Wingfield highlighted key findings from TAG's TB R&D report. The public sector accounted for 68.5% of TB research funding; the philanthropic sector accounted for 20%; the pharmaceutical and biotechnological sector accounted for 11%; and multilateral organizations accounted for 0.5%. The top five TB research donors in the world were NIH, the Gates Foundation, the Medical Research Council (MRC) in the United Kingdom, and CDC.

Of the overall TB R&D investment of $392.7 million in 2005, 30% was allocated to drugs; 24% to basic science; 18% to vaccines; 13% to operational research; 11% to applied, pre-clinical, infrastructure or unspecified activities; and 4% to diagnostics. TAG's estimate of ~$20 billion over the next decade to eliminate TB by 2050 was based on gaps among actual dollars allocated in FY'05, the Global Plan's 2006 estimate and a five-fold increase of 400%. TAG found the Global Plan's estimate to be inadequate in terms of basic and operational research.

Of TB basic science funding in the amount of ~$93.7 million, the public sector accounted for ~80% of spending in 2005 with NIH contributing ~71% of these dollars. Of TB diagnostic research funding in the amount of $16.4 million, the Gates Foundation accounted for 41.5% of spending in 2005 followed by NIH at 36.5%. Of TB drug research funding in the amount of ~$120 million, NIH accounted for 33.6% of spending in 2005 followed by another

company at 16.6%. These data show that a deficit of >$3 billion will occur if current funding to develop new and effective drugs to combat TB remains the same over the next decade.

Of TB vaccine research funding in the amount of ~$70 million, the Gates Foundation accounted for 41.1% of spending in 2005 followed by NIH at 34.5%. Of TB operational research funding in the amount of ~$50 million, MRC accounted for 37.5% of spending in 2005 followed by the Gates Foundation at 20.7% and CDC at 15.9%. The Global Plan does not mention operational research to ensure that new tools are relevant, appropriate and effective in communities.

Ms. Wingfield emphasized the need for non-USG agencies, private-sector organizations and foundations to make more investments in TB R&D. However, the role of multilateral organizations in serving as a major donor is unclear at this time. Although multilateral organizations play a significant role in providing guidance and technical assistance, these groups might not be appropriate as a primary funding source.

Ms. Wingfield conveyed that TAG's R&D report specifically focuses on NIH in some sections because NIH was ranked as the number 1 investor with spending of $\geq$$1 million on global TB R&D in 2005. However, NIH's investments primarily focused on TB basic science and drugs with no funding allocated to TB operational research, applied research or infrastructure development. The disparity between NIH's investments in basic science, drugs and vaccines for HIV versus TB is tremendous. NIH allocates more funding to smallpox and anthrax compared to TB, but TB accounts for more morbidity and mortality than these two diseases.

Data on NIH's spending on infectious diseases emphasize the critical need to leverage political will for both domestic and international TB at the same level as HIV. To achieve this goal, a strong activist and advocate movement with researchers, policymakers and communities will need to be widely launched. However, TAG is aware of the difficulty in building and sustaining TB advocacy over time because unlike HIV, TB is a curable disease. Cured TB patients typically have no interest in participating in community-based activist or advocacy efforts.

Ms. Wingfield summarized several conclusions from TAG's TB R&D report. A comprehensive global TB R&D agenda is urgently needed. Policymakers, researchers and activists should jointly develop a coordinated TB R&D plan for implementation at both global and national levels. The plan should clearly identify priorities, action steps and necessary resources to eliminate TB by 2050.

Industry should be more transparent about TB R&D investments. Reporting consistency is needed to better track and annually update TB R&D. All funding organizations should have greater involvement in TB R&D. Brazil, China, India, Russia, South Africa, Thailand and other emerging or high-burden countries should play a larger role in TB research and all other aspects of TB disease. A five-fold or 400% increase should be established as the

necessary minimum amount in annual TB R&D expenditures to achieve the goals outlined in the Global Plan II to eliminate TB by 2050.

Ms. Wingfield was pleased to announce that the Stop TB Partnership recently agreed to use TAG's TB R&D report as a resource in tracking annual investments of TB R&D. However, she reminded ACET about the lack of incentives offered to industry because TB is a disease of poor populations. As a result, she urged ACET to continue its advocacy role with researchers, policymakers and other key stakeholders to strongly encourage private and public sectors to strengthen TB drug research. Ms. Wingfield confirmed that TAG's TB R&D report would be distributed to ACET for review.

Update on the TB Epidemiologic Studies Consortium (TBESC)

Dr. Rachel Albalak, of DTBE, is the TBESC Project Officer. She covered the following areas in her update. CDC pointed out in its response to the 2000 IOM report on TB elimination in the United States that the nation lacks a clearly articulated research strategy. CDC also emphasized the need for a coordinated research plan to maximize efficiency, assure attention to activities of highest priority, and avoid duplication of effort.

To address these needs, CDC formed TBESC in 2001 with a mission to (1) conduct programmatically relevant economic, behavioral, epidemiologic, laboratory and operational research for TB prevention and control; (2) build research capacity in TB programs; (3) promote local and regional collaboration, (4) and strengthen the focus and coordination of TB research based on a comprehensive research agenda and a research prioritization process to guide funding decisions.

CDC also established TBESC in an effort to address the paradox in the United States regarding TB research. On the one hand, the United States has been successful in reducing national TB incidence. On the other hand, the number of cases in any single jurisdiction is too limited to support research needed to accelerate the decline. Fewer cases and resources call for an efficient approach to applied TB research.

TBESC pools expertise and TB cases from 20 sites across the United States and Canada. Five TBESC sites did not receive new funding in 2005 due to budget reductions. However, four of these five sites are continuing to conduct TBESC activities with CDC through no-cost extensions. The TBESC sites capture ~80% of all TB cases in the United States, but access to virtually all reported TB cases is available through a subcontracting mechanism.

TBESC's overarching research goals address innovation and refinement. Studies are conducted to identify new diagnostic tools and other breakthroughs to dramatically accelerate the decline in TB incidence. Programmatically relevant research is performed to make TB programs more effective even in the absence of breakthroughs. TBESC formed a

Translation of Research Into Practice Workgroup to collaborate with partners in facilitating translation of promising TBESC research findings into best practices. State and local TB control programs will implement these models to maximize effective TB control, elimination and patient care.

TBESC's top three priority areas for research in 2001-2004 were TB among foreign-born persons, latent TB infection (LTBI) and contact investigations. TBESC launched large studies and is beginning to collect and disseminate important findings from all three priority areas. Enrollment was completed in January 2007 for TBESC's study on ~1,700 foreign-born persons. Results from the study will play a key role in informing the creation of guidelines for TB among foreign-born persons. The study will also serve as the first representative picture of TB in this population in the United States. The development of several manuscripts from this study is underway.

Enrollment was completed for TBESC's TO#2 contact investigation study to provide critical information on biomarkers for susceptibility of TB. A manuscript from TBESC's LTBI study was recently published in 2006. The paper provides important data on the number of persons who were started on LTBI treatment in the United States and the types of clinics that treat LTBI. At this time, data collection has been completed for 13 TBESC studies and is ongoing in six studies. One TBESC study is in the protocol development phase and another study has been delayed due to problems with the diagnostic test.

In addition to the three priority areas, TBESC also conducted or is conducting a number of other studies that are relevant to and consistent with its mission:

- Immune markers for susceptibility to TB
- Pediatric TB
- Incorporation of HIV evaluation into contact investigations
- LTBI prevalence
- Regional capacity building
- Analysis of social networks
- Molecular epidemiology of MDR-TB
- New surveillance evaluation
- Barriers to TB treatment adherence
- TB knowledge, attitudes and beliefs among private providers
- Educational materials for Hispanic CBOs
- TB program self-evaluation
- African refugee women's project
- TK media for TB diagnosis
- New diagnostic tests in healthcare workers

In 2007, TBESC launched the Semiannual TBESC Advisory Review (STAR) to make funding requests for new research projects. TBESC engaged DTBE, NTCA and ACET in the new STAR process to develop, discuss and refine priority research questions and

formally call for research proposals. TBESC and its STAR partners convene face-to-face meetings to evaluate and rank proposals based on a research agenda established by TBESC and DTBE. Funding recommendations are then submitted to Dr. Castro, Director of DTBE.

TBESC and its STAR partners approved six new research studies for funding in FY'07: (1) risk factors for TB in African Americans (AAs); (2) the QuantiFERON-TB (QFT) Gold TB test in contact tracing; (3) QFT as an initial screening tool for U.S.-bound immigrants and the feasibility of follow-up in the United States; (4) treatment practices and outcomes for MDR-/XDR-TB; (5) evaluation of a new social network analysis tool; and (6) an ethnography study of TB among Karen-Burmese refugees. TBESC will undergo an external peer review process in August 2007 with a panel of three to four experts. TBESC plans to involve ACET in this effort.

A decision was made in 2007 to redirect unused dollars from completed TBESC research projects to establish a base budget. This approach allowed TBESC to maintain a reasonable and appropriate balance between research and infrastructure. However, level Congressional appropriations and increased costs have resulted in budget reductions to DTBE. As a result, DTBE asked TBESC to describe the potential implications of a 5% reduction per year. TBESC informed DTBE that its base budget would decrease from $7.8 million in FY'06 to $6 million in FY'11.

The budget constraints caused TBESC to assess the appropriateness of its current research model. TBESC identified its six strongest components that would need to be maintained for its current model: (1) a consensus process of establishing an agenda and identifying priorities; (2) input from ACET, NTCA, academic research groups, health departments and other key stakeholders; (3) an external peer review process for research projects; (4) development of consensus-based protocols; (5) an adequate data management component; and (6) capacity to ensure the completion of scientifically rigorous research projects.

Dr. Albalak concluded her update by describing TBESC's key challenges. Funding, regulatory and administration issues as well as recent changes in CDC's procedures have significantly increased TBESC's fiscal and administrative burden. Budget reductions may require a revision of TBESC's current research model or consideration of different approaches.

Despite these challenges, TBESC offers an efficient and flexible response to current problems in TB control as the epidemiology of TB changes. TBESC's strengths include an established funding mechanism; solid research and program expertise pooled across a large number of sites; excellent public-private collaborations; a strong infrastructure; and access to a diverse TB population of sufficient size.

Panel Presentation on the TB Trials Consortium (TBTC) Reviews

Dr. Andrew Vernon, of DTBE, led a panel presentation on an external review of TBTC's scientific agenda and a peer review of TBTC's intramural research program. He described two major research projects from TBTC's ten ongoing studies. Study 26 is evaluating an LTBI treatment regimen over three months with 12 doses. To date, 7,067 of 8,000 patients have been enrolled in the planned sample size. TBTC expects to complete enrollment for Study 26 at the end of December 2007.

Study 28 is substituting moxifloxacin for isoniazid in the first two months of TB therapy with a major outcome of sputum conversion at two months. Study 28 is one of a series of Phase II trials with a goal of identifying an appropriate regimen for a Phase III study of shortened treatment. Study 28 was completed in 2007 with 433 patients enrolled in 12 months. TBTC expects these results to be available in July 2007. Sub-studies will be conducted for both Studies 26 and 28. Efforts are underway to design the next round of Phase II studies. TBTC expects that the new Study 29 will provide a candidate regimen for a Phase III trial on shortened treatment.

Dr. Vernon explained the differences between the two recent TBTC reviews. For the agenda/external review, the TBTC Core Science Group initiated an external review of its scientific agenda to guide the next decade of TBTC research projects and enhance the existing infrastructure for re-competition of TBTC membership in 2009. The external review of TBTC was performed by 13 internationally recognized scientists, TB experts and partners.

For the peer/internal review, CDC policy requires peer review of all intramural research programs every five years to strengthen research programs. The peer review of TBTC was conducted by a subgroup of five reviewers from the external panel. An ACET member served on the peer review. TBTC plans to distribute reports of the two reviews to ACET for formal agreement in accordance with CDC policy.

Dr. William Burman is an ACET member and Chair of the TBTC Core Science Group (CSG). He reported that CSG conducted several activities in preparation for the external review. A detailed list of potential opportunities in TB therapeutic research was developed. Ongoing activities or future plans by other trial groups were identified. Conference calls were held to review major topics that should be addressed during the external review. Input was obtained from TBTC and the external review panel. The external review was discussed with internal partners and is now being presented to ACET.

CSG established several philosophic underpinnings to guide the external review. TBTC's research activities should be narrowly focused. TBTC should maintain its foundation in TB programs, build partnerships, and sustain and strengthen collaborations. CSG identified six major topics in TB therapeutics research to cover during the external review: LTBI, active

and drug-susceptible TB, active and drug-resistant TB, special populations, diagnostics, and decision analyses and modeling impact.

CSG agreed that four overarching questions should be asked to frame the external review: (1) What research should be performed? (2) What are TBTC's strengths? (3) What are TBTC's limitations? (4) What are the best strategies for TBTC to contribute to the global effort to improve TB treatment?

Dr. Burman's summary of CSG's key recommendations on the TBTC external review is outlined as follows:

For "LTBI," TBTC should ensure adequate enrollment of young children in Study 26 and completion of the pediatric pharmacokinetics study.

For "active TB," TBTC should focus on treatment-shortening regimens. The moxifloxacin study should be completed and rifamycin dosage should be optimized. Novel drug classes should be evaluated. Strategies should be developed to accelerate sequential Phase II studies by focusing on biomarkers of treatment effect and conducting pharmacokinetic and pharmacodynamic studies. Intermittent dosing should be assessed, but this should be viewed as a lower priority. Efforts should be made to rapidly advance from a very promising regimen in Phase II to a definitive evaluation in Phase III.

For "other potential TB trials," TBTC should take caution in conducting MDR-TB studies. This research should only be performed with increased funding and after broad consultation with other groups in the field. Involvement in HIV/TB co-infection studies should be continued because several important questions need to be evaluated. Studies on pediatric TB should be delayed. This research should only be performed after regimens have been evaluated in adults. Studies on diagnostics should be conducted in a very selective process. This research should only be performed in coordination and integration with a planned randomized trial.

For "overarching issues," TBTC should increase collaborative efforts in a number of areas. Laboratory scientists should be more engaged in studies on biomarkers. AIDS clinical trial groups should be involved in HIV/TB co-infection studies. The possibility of periodically sponsoring a global forum for TB trials should be considered to facilitate closer coordination with other TB trials groups. Collaborations should be strengthened with NIH to address funding problems. Current sites and their performance should be carefully reviewed. Persons with experience and knowledge in finance and business should be involved. The external review process should be conducted on an ongoing basis. The possibility of performing an outside review of individual study designs should be considered.

Dr. Elsa Villarino, of DTBE, reported that the review panel for TBTC's intramural research program recently gave DTBE preliminary results from the internal review. The review panel has not finalized the report, but Dr. Villarino highlighted some of the key comments. The

reviewers gave TBTC an excellent overall assessment, had a very positive impression of the value of TBTC, and reached strong consensus on the need to continue to support and protect this activity.

The reviewers noted that TBTC includes a unique group of investigators with diverse skills who partner with public health to accomplish important research in TB control. The reviewers agreed with TBTC's approach to target Phase II trials that would lead to the implementation of Phase III trials in the future. However, the reviewers pointed out that financial support for Phase III trials appears to be limited at this time. The reviewers viewed TBTC as a potential model for CDC to support other clinical trials activities.

DTBE asked TBTC to describe potential implications of a 5% budget cut per year over the next few years. TBTC informed DTBE that the 5% reduction would result in decreased capacity to enroll 530-550 patients per year and the closure of an additional three to four sites. TBTC had 28 clinical sites worldwide in 2004, but two sites were closed and funding to three sites was reduced in 2005-2006. These fiscal realities emphasize the need to either increase funding support or decrease TBTC activities and slow progress. TBTC is considering the possibility of changing its existing funding model beginning in 2009 to directly fund international sites.

Overall, ACET expressed strong concerns about the TBESC and TBTC budget cuts. Several members made comments on the series of TB research presentations by TAG, TBESC and TBTC.

- TBESC and TBTC should explore the possibility of performing broader infection control research.
- TBESC and TBTC should place stronger emphasis on interdisciplinary, trans-disciplinary and community-based participatory research to better translate research into practice at the community level. Lessons learned and best practices from HIV models should be reviewed and replicated in this effort.
- TBESC and TBTC should perform economic analyses to demonstrate the cost-effectiveness of TB research projects and studies.
- TBESC and TBTC should incorporate social epidemiology and social and cultural determinants into TB research projects and studies.

Panel Presentation on AA TB Intensification Projects

A panel presentation was made on three projects and an evaluation CDC funded to intensify TB prevention, control and elimination in AA communities.

Chicago Project. Ms. Gail Burns-Grant, of DTBE, announced that representatives of the TB Control Division in the City of Chicago Department of Public Health (CDPH) were unable

to attend the ACET meeting. As a result, she highlighted key outcomes from CDPH's demonstration project to intensify efforts for reducing TB rates in AA communities.

ACET called for action to address high rates of TB in the Southeastern United States in 2002. In response to ACET's recommendation, CDC funded three TB project sites in Chicago, Georgia and South Carolina through a competitive process to develop strategies and implement interventions for addressing TB in U.S.-born AAs in select jurisdictions within the respective project areas.

All three grantees were required to design the respective projects to achieve five key objectives. TB epidemiologic data would be analyzed to determine trends and identify target areas. Significant factors related to TB morbidity would be determined in the AA community, such as process and outcomes of treatment, contact investigations, and targeting and testing. Community-driven strategies and interventions would be developed and implemented to intensify efforts and accelerate the decline of TB in the AA community. A project evaluation would be completed. Findings of the project would be disseminated at the national level.

For objective 1, CDPH reviewed and analyzed both national and local TB epidemiologic data. National data on TB case rates by race/ethnicity in the United States from 1993-2005 showed a decrease in all racial/ethnic groups, but a large disparity between AAs and other racial/ethnic populations. National data also showed that AAs represented 28% of reported TB cases by race/ethnicity in the United States in 2005. Local data showed that TB case rates in Chicago decreased among AAs from 20.2/100,000 in 2000 to 16.9/100,000 in 2005 and among whites from 5.8/100,000 in 2000 to 2.8/100,000 in 2005. Chicago's reported TB cases among AAs substantially declined from 486 to 170 cases from 1993-2005.

For objective 2, CDPH identified significant factors related to TB morbidity. Selected risk factors associated with TB among U.S.-born AAs in Chicago in 2005 were any substance abuse in 31% of cases; excess alcohol use in 20% of cases; non-injecting drug use in 18% of cases; homelessness in 8% of cases; injecting drug use in 3% of cases; and incarceration in a correctional facility at the time of diagnosis in 3% of cases. The estimated TB/HIV co-infection rate in U.S.-born AAs in the city of Chicago was 20% on average from 1993-2005.

CDPH targeted its demonstration project to 13 zip code areas in Southside communities with high rates of TB. Common characteristics of the target sites included high unemployment rates, poverty, substance abuse, poor access to care, poorer health and lower life expectancy than whites, predominant AA populations, and stigma associated with TB. To implement the project, CDPH formed the Southside Community Task Force with representation by community leaders, former TB patients, academia, CBOs, private health providers, faith-based organizations (FBOs), business owners, correctional facilities, public health agencies and the media.

CDPH learned several lessons from key interviews and focus groups that were held with TB and STD staff, task force members and former TB patients. Partnerships should be established with sectors of the community with an interest in serving the AA community. A TB education and awareness campaign should be developed and launched. Community mistrust in healthcare providers should be addressed. Strategies should be developed to overcome the historical stigma and misconceptions that present barriers to persons seeking health care. The TB referral system for clients should be strengthened.

The task force separated into several subgroups to conduct a number of activities in response to findings from the interviews and focus groups. A TB curriculum was developed for medical providers, social service agencies and schools. TB messages and slogans were developed for target sites. Recommendations were made to assess and strengthen the referral system for HIV, mental health, substance abuse, shelters and other services. The community rejected the initial TB messages that were tested in pilot sites because the information was viewed as "watered down," "too generic," and ineffective for the inner city.

For objective 3, CDPH developed and implemented a number of interventions, including an "Eliminate TB in the AA Community" rap song; TB messages and slogans for 13 billboards on bus routes and park benches; a TB educational video; and a toll-free TB warm line for community members to obtain additional information about TB. A social marketing TB campaign was launched. A TB education and training course was created for stakeholders and medical providers. A TB education and art contest was sponsored in Chicago public schools with the winning logos displayed on CDPH T-shirts.

For objectives 4 and 5, CDPH submitted data from its AA TB intensification project for evaluation by the University of South Carolina. The results were then forwarded to DTBE for national dissemination in December 2005. A meta-evaluation was conducted and completed in 2006 across all project sites to measure the impact of the interventions on the cultural and linguistic competency of TB programs. CDPH expects to submit its final report to DTBE in the spring of 2007.

CDPH faced a number of challenges in developing and implementing the project. Contractual issues delayed activities for nine months. CDC's supplemental funding ended in December 2006. TB funding has decreased at all levels. The number of dedicated TB project staff to address TB in the AA community has declined. Despite these challenges, CDPH is taking advantage of several available opportunities. Community involvement has been sustained through the task force. Other funding streams will be explored and CDC's guide and toolkit will be used to support activities in the AA community.

Collaborations will be continued with national TB project sites and other programs with a disproportionate burden of disease in the AA community, such as HIV and STD programs. Objectives will be refined to continue to reduce TB in the AA community in accordance with the indicator in CDC's 2005-2009 cooperative agreement for TB control and prevention. A number of CDC mechanisms, opportunities and venues will be used to disseminate findings

from the project. Lessons learned from CDC studies and other initiatives will be applied as resources allow. Ms. Burns-Grant concluded her overview by playing CDPH's "Eliminate TB in the AA Community" rap song for ACET.

South Carolina Project. Mr. Joseph Kinney is an ACET member and a Program Consultant in the TB Control Division of the South Carolina Department of Health and Environmental Control (SCDHEC). He reported that SCDHEC designed its AA TB intensification project to obtain information in three key areas: (1) the association between knowledge, beliefs and values of TB and race; (2) the influence of socio-cultural factors on TB incidence and prevalence; and (3) the implications of these findings in developing intervention strategies.

SCDHEC also developed the project to achieve four major outcomes. An overview of the population, health status, knowledge, beliefs and values would be provided. The need for specific population-based services would be assessed and described. Barriers and enabling mechanisms would be identified to address the knowledge, values and belief systems of AAs diagnosed with or at risk for TB. The role of socioeconomic and cultural factors on the incidence and prevalence rates of all South Carolina residents with a diagnosis of TB from 1996-2001 would be assessed and described. SCDHEC conducted face-to-face interviews with persons diagnosed with TB during this time period.

SCDHEC analyzed state TB epidemiologic data to determine trends and identify target areas for the project. Data on TB case rates in South Carolina showed that six counties had case rates >15.1/100,000 in 2005. Of these six counties, SCDHEC selected four with case rates >15.9/100,000 in 2005.

Key findings from SCDHEC's data collection and analysis are summarized as follows. Among AAs, 52.1% of TB cases live in census tracts where the unemployment rate equals or exceeds 8.5% of the state average. In contrast, only 16.4% of white TB cases occur in census tracts where the unemployment rate equals or exceeds 8.5%. The percentage of unemployed AAs is higher in high-burden areas in the Northeast Corridor than in the remainder of the state. Unemployment among AAs substantially increased between 1990 and 2000 in the high-burden health districts of Pee Dee and Waccamaw Counties.

Fear was found to be associated with the lack of information. The expectation of rejection from the broader community caused many persons who were diagnosed with TB to isolate themselves from support systems. Persons who were diagnosed with TB expressed anger at the diagnosis, confusion about the source of exposure, fear of not being cured, danger of losing their jobs, and stigma.

SCDHEC made several recommendations based on the data collection results. Treatment approaches should be developed and implemented that reinforce the stigma of TB. Issues related to continuity and completion of LTBI should be addressed. Organizational personnel should be shifted to better integrate services across programs. Use of

paraprofessionals should be expanded. TB control staff should be used to address the needs of patients in a culturally sensitive and compassionate manner. Partnerships between primary care services and public health should be maintained. Culturally competent and suitable materials should be developed and disseminated. Opportunities to bill Medicaid for TB services should continue to be explored.

SCDHEC developed and implemented several strategies and interventions to support its AA TB intensification project. Collaborations were established with a number of state and local partners to ensure the availability of medical services for TB patients with no access to a medical home. Primary centers will coordinate LTBI screening, evaluation and treatment with SCDHEC's TB program.

To increase community awareness of TB prevention, care and treatment, a health educator was deployed in the field. Geographic information system (GIS) mapping was used to identify and select communities at high risk for exposure to TB. TB notices were placed on billboards and messages were delivered in a magazine targeted to AAs. Information was disseminated about TB through posters, brochures and targeted handouts. The materials were designed to be culturally appropriate for TB patients, their families and the community.

Mr. Kinney concluded his overview by describing challenges in further implementation of SCDHEC's AA TB intensification project. Medicaid funding is undergoing changes and reductions. State governmental agencies are being reorganized, but these new structures might provide opportunities for personnel from other programs to provide expertise to the TB program. TB controllers and providers have not yet identified areas they are willing to share and sacrifice to intensify TB prevention, control and elimination in AA communities.

Georgia Project. Mr. Kenneth Johnson, of the Georgia Department of Human Resources (GDHR), reported that GDHR designed its AA TB intensification project to identify gaps, develop opportunities for TB prevention, and reduce disparities in TB. GDHR analyzed national, state and local TB epidemiologic data to determine trends and identify target areas for the project. Although national data showed that AAs represented 28% of reported TB cases by race/ethnicity in the United States in 2005, AAs accounted for 45% of all U.S.-born cases.

State data showed that Georgia's TB case rate per 100,000 population in 2005 was higher than the national average with Fulton County having the highest case rate of all 18 health districts in the state. Local data showed that AAs accounted for 73% of TB cases in Fulton County in 2006.

After receiving funding from CDC in August 2002, GDHR held focus groups, performed a needs assessment, and formed the Controlling and Eliminating TB in AA Communities (CETBA) Advisory Board. These activities were used as the basis for GDHR developing a comprehensive plan of action to accelerate the reduction of TB cases among AAs in Fulton County, Georgia.

GDHR established CETBA with representation by state and local health departments, social service and housing agencies, CBOs, FBOs, private health groups, professional organizations, academia, correctional facilities, community leaders and TB stakeholders. CETBA held monthly meetings in close collaboration with the GDHR TB program to close gaps and identify opportunities for TB prevention and control in Fulton County.

GDHR and CETBA conducted several activities to support the project. A needs assessment was performed that emphasized the need to increase TB knowledge, awareness and education in the AA community. A communications and awareness program was developed based on results of the needs assessment and targeted to eight zip codes in Fulton County with higher TB morbidity compared to the state of Georgia. However, information was distributed throughout the entire county.

The "Hear, Act, Learn, Treat (HALT) TB" media campaign was launched on World TB Day on March 24, 2005 to inform the community about risk factors associated with TB. The HALT TB campaign included street, homeless shelter and agency outreach; advertising on bus shelters and park benches; and informational videos.

Former TB patients who had completed LTBI treatment were hired and trained as peer workers to serve as a resource to clients currently undergoing LTBI treatment. Peer educators reminded adherent clients about upcoming appointments through telephone calls and follow-up letters. Peer educators also conducted field visits to locate and encourage non-adherent clients to present to the clinic for their scheduled appointments. Peer educators met clients at the clinic to establish personal relationships and document treatment outcomes in client charts. Because many peer educators lived in the same communities as current TB patients, the close proximity facilitated the formation of a bond, understanding and greater treatment adherence.

An external contractor was hired to evaluate several programmatic activities of the project. For the peer education program, the evaluation showed that the established goals and objectives were successfully achieved. The clinic director, peer educators and clients who received services all expressed tremendous satisfaction with the project. An analysis of the client charts indicated the success of peer educators in reaching hard-to-reach clients. Relationships between the peer educators and clients were developed and fostered by using standardized methods to increase treatment adherence, such as reminders through telephone calls and follow-up letters and field visits.

For the TB communications and awareness campaign, the evaluation showed that a methodology was designed to obtain baseline information and perspectives through a literature review, focus groups, the media, field observations and intercept interviews. Implementation and results of the project were assessed through observance of World TB Day, field site reviews, and street team and intercept interviews.

GDHR reached several conclusions after implementing its AA TB intensification project. The interventions could be tailored for replication in other parts of the state and throughout the country to reduce TB rates in the AA population. For example, GDHR recently provided Mississippi with HALT TB campaign materials for use in World TB Day in 2007. A comparison of 2004-2005 data showed more consistency above the 55% completion rate among high-risk LTBI patients, including recent converters and HIV-positive patients. A comparison of 2003-2005 data also showed more consistency above the 63% completion rate among contacts.

AAs represented 45% of the population in Fulton County and accounted for 82% of TB cases in 2001 before implementation of the project. However, the proportion of TB cases among AAs in Fulton County decreased to 68% in 2005 after implementation of the project. New reported cases, case rates and cases among U.S.-born AAs have been steadily declining in Fulton County since 2003. The number of AA TB cases in Fulton County decreased by 39% from 111 cases to 68 cases.

GDHR established partnerships with CBOs, academic institutions, healthcare providers, hospitals, FBOs, and other professional associations with a mission to advance the health and wellness of AAs in Fulton County. The communications and awareness campaign resulted in the design and production of attractive and compelling educational materials that have been widely disseminated through a variety of mechanisms in Fulton County. Utilization of diverse venues to communicate messages might have played a key role in raising awareness about the identification and treatment of TB.

GDHR established solid approaches for its AA TB intensification project, but these strategies will require additional resources to be sustained. CDC granted GDHR an extension in 2006 to maintain the peer educators for an additional year. Fulton County used these funds to hire one peer educator, but was unable to hire all three persons. GDHR's application to TB Leads for additional funding was denied.

Mr. Johnson concluded his overview by presenting a video of the HALT TB campaign. He was proud to announce that the campaign won a "Bronze Telly Award" to honor excellence in local, regional and cable television commercials, non-broadcast videos and television programs. The Telly is one of the most sought after awards by international firms, local production companies, advertising agencies and other industry leaders. The 13,000 entries that were submitted for the Telly were from all 50 states and 30 countries around the world.

Evaluation Project. Dr. Ana Lopez-De Fede is an ACET member and Director of the Division of Health and Family Studies at the University of South Carolina Institute for Families in Society (IFS). IFS was contracted to conduct the evaluation of the three AA TB intensification projects in Chicago, Georgia and South Carolina. Dr. Lopez-De Fede highlighted key findings from the evaluation.

The three project sites provided IFS with five-year prevalence data on TB, responses from key informant and individual interviews, findings from focus groups and all other data associated with the projects. IFS analyzed the data to identify common trends and issues across the three projects.

Part 1 of the evaluation focused on the socioeconomic status (SES) of health disparities and TB. The impact of SES on health disparities was measured based on income inequality, social capital, and factors related to medical care and lifestyle. Although researchers have extensively examined the association between SES and HIV/AIDS, cardiovascular disease, diabetes and other disease entities, the relationship between SES and TB infection in the United States has not been analyzed.

The general trend in TB incidence is apparent. For AAs and whites separately and for all races combined, TB incidence rates are higher in areas with low SES. AAs typically live in zip code areas with low SES in terms of high rates of poverty and social deprivation. These findings were consistent among all three project sites. As a result, additional research is needed to clarify the association between TB and SES factors, including poverty, unemployment, educational attainment, living arrangements, neighborhood social capacity, and culturally-specific behaviors, attitudes and beliefs regarding TB.

Part 2 of the evaluation focused on factors that influence access to care for persons with or at risk for TB. A qualitative analysis was designed to answer three key questions: (1) What is the knowledge level of TB in AA communities? (2) What are the challenges faced by AAs with or at risk for TB? (3) What approaches would facilitate access and continuity of care for AAs with or at risk for TB?

To conduct this part of the evaluation, IFS coded and analyzed data submitted by the project sites from 110 individual interviews, three focus groups with 100 participants, and ten key informant interviews with persons who could influence policy. IFS used a constant comparative method to analyze data, develop a cultural consensus model, and compare persons with common neighborhood characteristics across the three project sites.

IFS used the coded and analyzed data to obtain information in three major clusters. For knowledge and beliefs about the causes and symptoms of TB, AAs in the three project sites had much lower knowledge of TB compared to other racial groups, including foreign-born persons. AAs in the two sites in the South had less knowledge about the causes and symptoms of TB compared to other racial groups. IFS found these results to be consistent with national survey data.

For beliefs about prevention, treatment and stigma of TB, some AAs still had historical beliefs about TB. For example, some AAs in rural South Carolina believed that local authorities would place TB patients in an institution. AAs in all three project sites had limited knowledge about the consistency of TB treatment. Many AAs in all three project sites were unable to distinguish between stigma associated with TB and HIV. Access to

maternal and child health programs in health departments further increased stigma related to AAs obtaining timely care.

For systems of care, AAs in all three sites needed education on TB prevention and completion of treatment. AAs across the project sites described different experiences with healthcare providers, but most AA males reported negative experiences. AA males described their isolation from traditional systems of care within health departments because these agencies primarily focus on HIV, STDs, pregnancy, or other specific services for women and children. AA males often viewed DOT workers as part of health departments who exacerbated negative beliefs, experiences and stigma associated with TB.

IFS evaluated recommendations the project sites made on the prevention of TB. The focus on concerns about high TB rates should be shifted to develop strategies that encourage early treatment and adherence. Educational interventions are essential and should incorporate cultural beliefs and preferences, lifestyle behaviors and risk factors. New strategies and approaches should be developed and incorporated to provide TB treatment that is culturally-appropriate, targeted and essential.

Healthcare providers should be educated on approaches to outreach to, engage and maintain ongoing client contact. Communities will be unable to continue to support, embrace, understand and advocate for TB elimination without these strategies. A community-based health model should be developed that covers comprehensive health care beyond TB.

To support this effort, NCHHSTP should review and replicate its community-based models that were developed and successfully implemented to enforce, support, encourage and fund HIV/AIDS and STDs. Training should be provided on GIS and deprivation models that allow for resources to be identified and leveraged within specific communities. Dr. Lopez-De Fede concluded her overview by commending the Chicago, Georgia and South Carolina sites for embracing and extensively involving the community in all aspects of the projects from development to implementation.

ACET applauded the Chicago, Georgia and South Carolina sites for designing and conducting creative, exciting and innovative projects to intensify TB prevention, control and elimination activities in AA communities. Several members made suggestions that should be considered to further advance this initiative.

- ACET should take a leadership role in its capacity as a federal advisory committee for TB elimination to develop targeted strategies to address the high burden of TB in the AA community. Most notably, U.S.-born AAs bear ~50% of the TB burden in the United States, but no effective approaches have been created to date to address this issue.

- ACET should develop regional strategies to address the disproportionate burden of TB in the AA community because the Southeast accounts for 50%-75% of this rate in the United States.
- DTBE should encourage the Chicago and Georgia project sites to replicate South Carolina's model of partnering with state Primary Healthcare Associations. All three sites should also collaborate with Health Resources and Services Administration (HRSA) community health centers (CHCs) to implement the project activities on a broader scale. The project sites should use Dr. Theresa Watkins-Bryant, ACET's *ex-officio* representative to HRSA, as a resource in contacting these agencies.
- DTBE should assist the three sites in publishing findings from the projects in peer-reviewed journals. This approach would expand efforts to raise awareness about the TB problem in the AA community among providers throughout the country.
- DTBE should advise the three project sites to collect HIV data on all TB patients because 2006 marked the first year with a decline in HIV reporting status among TB patients. At this time, the HIV status is unknown in ~33% of TB patients.
- DTBE should advise the three project sites to incorporate results from the projects into universal genotyping. This approach could provide a better understanding of whether recent transmission or activation is the cause of the TB disparity in the AA population.

Dr. Castro pointed out that several articles have been published in the past on TB disparities in racial/ethnic groups, but he agreed with ACET's suggestion to compile and publish new data from the three AA TB intensification projects in peer-reviewed journals. These papers should particularly highlight the findings, interventions and outcomes of the projects.

Update on the "Stop TB in the AA Community" Summit

Dr. Nickolas DeLuca, of DTBE, presented preliminary evaluation findings from the summit that was held in May 2006. CDC and RTI International jointly sponsored the summit with one-time funding that NCHHSTP awarded in 2003 under TBESC Task Order 11. The overarching purpose of the summit was to address the disproportionate impact of TB on racial/ethnical minority groups. Racial/ethnic minority groups accounted for 82% of all reported TB cases in 2005 and AAs accounted for 45% of TB cases among U.S.-born persons. The TB case rate of 8.9/100,000 among U.S.-born AAs is >8 times higher than the rate of 1.1/100,000 among U.S.-born whites. This disparity has been consistent since 1993.

ACET prioritized TB in AAs in 2002 by calling for presentations, establishing a workgroup on this topic, and formally requesting additional research and resources. CDC and ACET jointly convened a national summit in May 2003 to raise awareness of the TB disparity. A follow-up summit was held in May 2006 to raise awareness of the problem, build on accomplishments from the 2003 meeting, and create linkages and establish networks to facilitate the development of ongoing strategies to address the problem.

Participants at the 2006 summit included >100 representatives from CDC, TB prevention programs, professional organizations, academic institutions, local and national advocacy organizations, HHS state and regional minority health consultants, civic groups, CBOs, FBOs and fraternities. During the summit, the participants were divided into breakout groups based on organizational type to facilitate collaborations with peers. Each breakout group was charged with devising action plans with a list of options that could be implemented in the upcoming year without additional funding from CDC.

CDC evaluated the outcomes of the summit and implementation of the action plans. CDC collected data through e-mail communications with each of the six breakout groups and conference calls four to five months after the summit. To assess the completed activities and action items, the data were grouped into six qualitative categories.

For "education and awareness" action items, CDC's educational materials were distributed at exhibits and health fairs, included in conference packets of national meetings held by professional organizations, and directly provided to CBOs. Dissemination of the *TB Challenge Newsletter* was increased. A "TB in the AA Community" web site and listserv were established. A flyer was created to provide more information about the web site and listserv.

For "networking" action items, new contacts were formed between TB and other programs at the local level, such as diabetes and HIV. Linkages were made between state and regional HHS minority health consultants and TB programs. Communication and collaboration were improved among CDC divisions. The Concerned Black Clergy, minority health consultants and other new partners were engaged.

For "capacity building" action items, TB in AAs was included in CDC's TB program manager course for the first time and also was incorporated into local training sessions. Regional Training and Medical Consultation Centers (RTMCCs) were engaged. The Southeast RTMCC dedicated resources to create educational materials and a toolkit.

For "system change" action items, TB and HIV services and education were integrated. TB programs increased access to services by offering flexible time to allow outreach workers to better serve patients. TB testing was added to a mobile medical unit that serves homeless and substance abuse facilities. A TB testing protocol was initiated in an emergency room. Surveillance measures were changed to more clearly distinguish between TB in U.S.-born and foreign-born AAs.

For "publicity" action items, a variety of venues were used to create post-summit posters, make presentations, publish articles, or post links on the web sites of organizational partners. The publicity mechanisms included an NTCA meeting, the CDC Office of Health Disparity lecture series, an IUATLD North American Region meeting in Vancouver, ACET, and *TB Notes* and *TB Challenge*.

For "political will" action items," a two-hour breakout session on TB in AAs was added to NTCA's 2007 meeting. Feedback from some participants at the summit confirmed that the event was beneficial in raising awareness about TB, networking with other groups, and generating actions to address TB.

Overall, the summit resulted in several positive outcomes. Dialogue and interest about the TB disparity in the AA community were rekindled across institutions. New partners were engaged to increase awareness of and address the health disparity. Action items completed to date demonstrated that activities for TB in the AA community can be conducted with limited resources. However, additional resources and commitment will be needed to sustain momentum.

Dr. DeLuca concluded his update by describing next steps in this initiative. A second round of follow-up conference calls will be held with summit participants to coincide with the one-year anniversary of the May 2006 summit. Persons will be encouraged to complete additional action items. The listserv and web site will be used to maintain communication with summit participants and other persons with an interest in this topic. Funds were awarded to TBESC's national, multi-year and multimillion dollar epidemiologic study to determine early diagnosis, prevention and treatment of TB in the AA community.

DTBE has committed to conducting and publishing an analysis of the Chicago, Georgia and South Carolina AA TB intensification projects in the *MMWR* or a peer-reviewed journal. An intervention-focused proposal was submitted to the TBESC STAR process to apply lessons learned from the three intensification projects into actual practice and expand these activities to other sites throughout the country. However, the proposal was not accepted for funding. Efforts will be made to identify resources for a follow-up summit.

Overview of the Task Order 11 Formative Research Results

Dr. Rachel Royce, of RTI International, summarized preliminary results from the formative research phase of Task Order 11. RTI is conducting the study under TBESC to address the TB disparity in the AA community in eight Southeastern (SE-8) states. The overarching goal of the study is to investigate multi-level facilitators and barriers to TB services for AAs in high-morbidity rural and urban counties to aid in devising effective interventions. Of 14,517 TB cases reported in 2004, U.S.-born cases represented 46% and foreign-born

cases represented 54%. AAs accounted for 45% of U.S.-born cases and SE-8 accounted for 35% of all U.S.-born AA cases.

RTI designed a TB disparity conceptual model to better understand factors that are responsible for the active TB and LTBI disparity in AAs. The model showed that the most important factors contributing to the TB disparity in AAs were a higher community prevalence; longer periods of time to accurately detect and treat cases; and poorer rates of treatment initiation, adherence and completion. The model emphasized the need to develop interventions at social, cultural and structural levels.

The cohort of the Task Order 11 study was divided into two major groups. The AA population included AAs with active TB, LTBI and a high risk for TB. The provider population included TB control program staff, community health providers and community leaders. The study sites were selected through a process of mapping cases; quantifying the burden; and creating a TB disparity score with the number of cases in AAs, rates of cases per 100,000 population, and the ratio of the TB rate in AAs compared to whites.

All 688 counties in SE-8 were ranked according to the disparity score to assist in targeting counties with the highest TB morbidity. The study sites were selected based on a number of considerations, such as the TB disparity score rankings, a balance between rural and urban sites, ability to participate, political issues, and the number of cases available to interview.

Three sites were selected for the study based on these factors. Montgomery County, North Carolina is a rural site with a TB rate of 141/100,000 and a TB disparity score ranking of 3rd. Dekalb County, Georgia is an urban site with a TB rate of 29.2/100,000 and a TB disparity score ranking of 36th. Davidson County, Tennessee is an urban site with a TB rate of 29.7/100,000 and a TB disparity score ranking of 48th. Of 131 total participants, 38 were from the North Carolina site, 40 were from the Georgia site, and 53 were from the Tennessee site. Individual qualitative interviews, open-ended individual interviews and focus groups were used to obtain information from the study participants in the following six areas.

For “community issues,” housing, employment, finances, mental health problems and substance abuse often took precedence over health concerns and affected the diagnosis and treatment of TB according to patients and providers. Patients and providers mentioned pressing health concerns that were perceived to have higher prevalence in the community, such as diabetes, HIV and obesity.

For “diagnosis and treatment of active TB,” patients were often symptomatic at diagnosis, but discounted these symptoms due to co-morbid conditions, including diabetes, high blood pressure, substance abuse, mental health problems and HIV. TB symptoms were not the dominant precipitating event around diagnosis.

Precipitating events leading to diagnosis of active TB and LTBI included job requirements, word-of-mouth or hearsay about other TB cases, diagnosis for other acute and chronic illnesses, requirements for substance abuse, mental health or correctional facilities, and contact investigations. Most patients reported few problems taking TB and LTBI medications. Side effects for active TB treatment were common, but were not described as debilitating.

For "TB knowledge and stigma," only 28% of active TB and LTBI patients demonstrated knowledge of TB when asked. Many patients, at-risk persons and community leaders had no knowledge about the difference between LTBI and TB disease. Several participants had misconceptions about TB prognosis, transmission and prevention, such as TB being an incurable disease and a virus that could be transmitted through smoking, drinking behind others, pollution or kissing. The injection for the tuberculin skin test (TST) was also believed to directly prevent TB.

At-risk community members had strong beliefs about TB transmission. All participants cited situations in which community members expressed fear about TB. Many participants expressed fear of being exposed to infectious persons who were either unaware of or were purposely concealing their infectiousness. Some at-risk persons and community leaders believed that the practice of sending active TB patients to sanitariums should be reinstated to protect community members. TB or LTBI patients generally had no interest in informing others about their diagnosis due to the fear of being stigmatized by the community. Several patients cited instances in which they were shunned or knew of others who were shunned because of TB.

For "strategies to reach AAs," low literacy among patients was found to be a barrier to TB education efforts. Most providers believed that the primary sources of information for community members were hearsay, word-of-mouth and television. However, patients reported that physicians were their primary source of information. Patients noted that their preferred method to receive information was through pamphlets and brochures supplemented with face-to-face communication with a medical provider.

For "approaches to improve TB services and treatment completion," patients reported that they often did not fully understand information received from health providers. Several providers described issues related to contact investigations, staffing limitations, and lack of trust by patients of TB control staff. The use of multiple nicknames hindered the capacity of providers to identify potentially exposed persons.

Dr. Royce summarized key conclusions from the formative research phase of the study. Patients had other community concerns that took priority over health issues. Many TB and LTBI patients reported several co-morbidities that impact or might affect the diagnosis of TB. Strategies to raise TB awareness will lead to increased TB knowledge and a decrease in fear and stigma.

A disconnect exists between the perceptions and expectations of providers and patients in patient education. On the one hand, providers indicated that they should play a secondary role in patient education. On the other hand, patients expected and preferred providers to play a direct role in patient education. TB education efforts should be tailored to the literacy levels and preferences of community members.

RTI's next steps in Task Order 11 will be to conduct the intervention phase of the study based on the formative research results, findings from the AA TB intensification projects, and experiences of other activities to address the TB disparity in AAs. The intervention phase also might include efforts to strengthen partnerships among TB control programs, AAs, healthcare providers and the community to improve communication, knowledge and awareness of TB.

Dr. Royce concluded her overview by informing ACET that TBESC formed a workgroup to focus on TB in AAs and include this topic in the TBESC research agenda. Several proposals submitted to TBESC for FY'07 funding through the STAR process reflected the need to conduct more research on TB in AAs.

Drs. Castro and DeLuca described several options for ACET to consider in its ongoing dialogue about strategies to address the TB disparity in the AA community. DTBE should explore the possibility of replicating the HIV model of directly-funded CBOs. With this approach, DTBE could allocate funds directly to CBOs to expand findings from the three AA TB intensification projects and conduct other demonstration projects. DTBE should also duplicate the HIV model in which epidemiologic data were gathered and distributed to external HIV partners to mobilize resources, directly fund CBOs and implement community-based interventions.

Overview of CureTB

Dr. Kathleen Moser, of the TB and Refugee Health Branch in the San Diego County Health and Human Services Agency, reported that CureTB is a part of the San Diego County TB Program. CureTB has been operating since 1997 and has built strong relationships and credibility in both the United States and Mexico over this period of time. CureTB serves as a direct communication system among providers in the United States and Mexico, the Mexican National TB Program, and TB patients who migrate between the two countries. Both U.S. and Mexico providers are given information about the patient's clinical history and TB treatment.

CureTB collects and maintains data on outcomes of all patients with verified active TB disease who are referred across the border. These data are stratified by U.S. Immigration and Customs Enforcement (ICE) cases versus non-ICE cases with the following outcomes: TB treatment completed, refused or ongoing; patient died, lost or returned; insufficient initial

information; and treatment not recommended. In 2004, treatment was completed by 46% of 58 ICE cases and 65% of 91 non-ICE cases.

Dr. Moser described CureTB's four major challenges at this time. For issue 1, CureTB is challenged by dramatic budget cuts. CureTB is primarily funded by the state of California and San Diego County cooperative agreement dollars. These two sources accounted for $252,000 to CureTB in 2006. San Diego County TB cooperative agreement funds decreased from ~$2.4 million in 2004 to ~$1.7 million in 2007. The decrease was due to the termination of the targeted testing program, a reduction in laboratory services and various rescissions. Budget cuts have led to CureTB's current operations with a skeletal staff of only three personnel.

Budget cuts have also resulted in the inability to continue to print the binational TB card in the United States. CureTB launched the Binational Card Project in March 2003 to establish relationships, improve operations and collect outcomes. The binational card was developed and has been in use since 1999 to provide TB patients with contact information in both the United States and Mexico. The project also allowed CureTB, TBNet, CDC and the Mexican National TB Program to streamline operations and develop a recognizable bilateral program. San Diego is exploring the possibility of allocating funds to ensure continued printing of the binational card.

For issue 2, CureTB is challenged by arranging for continued TB treatment and follow-up care of non-ICE detainees until deportation. For example, a Mexican male 22 years of age was recently being smuggled into the United States, detained by the U.S. Customs and Border Protection (CBP) as a material witness, and found to have smear-positive pulmonary TB. Because CBP no longer needed the detainee as a material witness, San Diego County was faced with a dilemma. On the one hand, the local TB control program could assume responsibility for the detainee's TB care, treatment, housing and other costs, security issues and flight risk. On the other hand, the detainee could be deported, transmit TB in a Mexican city, and eventually return to the United States.

For issue 3, CureTB is challenged by addressing *Mycobacterium bovis*. Of 782 culture-proven TB cases in San Diego County in 2004-2006, 11% were *Mycobacterium bovis*, 98% were Hispanic, 59% were born in Mexico, 20% were co-infected with HIV, 25% were children <15 years of age, and 45% had only an extrapulmonary site.

For issue 4, CureTB is challenged by inconsistent and inadequate administration of DOT in Mexico. CureTB received three-year funding from USAID in the amount of $323,000 to build capacity to treat MDR-TB cases in Baja, California and strengthen DOT in Mexico. Under this project, CureTB will provide medications to patients and closely collaborate with physicians in Mexico to strengthen skills in treating and managing MDR-TB cases.

The ages of the five patients in the project range from 22-62 years. All of the patients have extremely high levels of resistance, but four of the five patients were treated with first-line

drugs for a number of years by the main government program in Mexico. CureTB is attempting to qualify for Green Light drugs to sustain the project in Northern Baja, California.

Cure TB should not be supported with San Diego County's Cooperative Agreement funds that are meant to support their local priorities. If the country truly values Cure TB, the program should be supported by additional funds that could be added to San Diego's COAG or through a separate funding mechanism.

CureTB should be provided with necessary resources, funding and expertise to develop an efficient and secure data system to transmit x-rays and other clinical data to Mexico. For example, many agencies and organizations in Mexico still receive clinical data through a combined telephone/facsimile line. CureTB is often challenged by securing an international telephone line between the United States and Mexico. A new Binational Adherence Workgroup should be established to develop patient-centered solutions and funding estimates. A new Binational Workgroup should be formed to review economic and health issues of the fresh cheese industry. DOT should be supported in Mexico.

Overview of TBNet

Ms. Deliana Garcia, Director of the Migrant Clinicians Network, described activities MCN conducts under TBNet to provide trans-border migration care to mobile TB patients. MCN is a national clinical network that was founded in 1984. MCN is currently represented by 2,000 clinician members and is the oldest and largest clinical network dedicated to the mobile underserved population. MCN's primary constituents are clinicians who work in federally-funded CHCs and health departments at state and local levels.

Mexico is one of the principal countries with migrants in the United States. The number of migrants from Mexico increased from 300,000 in the 1990s to 1.4 million in 2004. Of Mexican migrants in the 1990s, 4% would not return to Mexico compared to 10% who would not return to Mexico presently. California, Texas, Arizona, Illinois and New York rank as the top five states with the largest number of immigrants from Mexico.

Of 26.2 million Mexicans who live in the United States, 11.5% are of Mexican descent, 2.3% are naturalized citizens, 2.1% are residents and 10.3% are undocumented. Of the 10.3% undocumented Mexicans in the United States, 3% are indigenous. Of Mexicans who migrate to the United States, 62.5% are 20-44 years, 13.6% are 45-59 years of age, 12.6% are 10-19 years of age, 6.1% are $\geq$60 years of age, and 5.1% are <10 years of age.

International migration involving annual movement of tens of millions of persons has become the norm, but actions have been taken only recently to assess the public health implications of this trend. International migration is still treated as an aberration rather than

an ongoing and significant public health event. For example, of 1,835 leprosy cases reported in the United States from 1971-1981, only 25% of imported cases were known to have leprosy at U.S. entry and cases were still reported ten years after U.S. arrival in the remaining 75% of cases.

In terms of TB, foreign-born persons accounted for the majority of cases for the first time since 2002. In 2004, 53.7% of 14,511 active TB cases in the United States were among foreign-born persons. Of the foreign-born cases, 26% were from Mexico with undocumented residents representing a significant proportion of these cases. Central Americans who migrate to the United States through Mexico add to Mexico's burden of disease.

Several binational TB projects have been ongoing since 1991 in both the United States and Mexico. Through the Binational Bridge Case Management Program (BBCMP) that was initiated under TBNet in 1996, >2,700 patients have been managed for 30 countries. Among migratory patients treated for active TB disease in 2005, the completion rate was 71.4%.

BBCMP is being used to increase TBNet's focus and activities beyond the transfer of medical records, communications with National TB Programs in other countries, verification of contact information of clients, and referrals to a source of care. TBNet provides care-coordination services over the telephone by informing the sending or receiving clinic about the client's treatment completion or duration of treatment. TBNet identifies a treatment provider in the new location. TBNet obtains consent from clients to transfer medical records and ensure continued care when clients move. TBNet educates clients who are suspected or known to have active TB about treatment, the importance of completing treatment, and the need to remain in care.

TBNet asks clients to provide information in several areas, including country of origin, length of time in the area, future plans, frequency of moving, employment, and reliable contact information for themselves and persons who will always have knowledge of their whereabouts. TBNet maintains contact with both the provider and client for the duration of TB treatment and informs the provider about the client's final treatment outcome. TBNet communicates with all known contacts of the client if the client discontinues or fails to present for TB treatment.

Ms. Garcia concluded her overview by regrettably informing ACET that TBNet has lost its funding source. The Division of Immigration Health Services (DIHS) is a major user of TBNet's services and has continued to provide support. However, DIHS's continued support accounts for 50% of the TBNet patient population and does not cover the remaining 50% of patients from health departments and CHCs across the United States.

ACET acknowledged the tremendous impact of CureTB and TBNet on TB control programs throughout the country. Several members made suggestions to leverage resources for CureTB and TBNet.

- CureTB and TBNet should explore the possibility of linking to and building on successful interventions Project Concern International has implemented. Project Concern has traditionally focused on child survival, sanitation and other non-TB issues and targets populations with different cultural backgrounds. However, CureTB and TBNet could apply lessons learned from these initiatives to address the TB disparity in racial/ethnic groups.
- CDC should explore the possibility of using funds from the expansion of quarantine stations and global disease detection initiatives to support ongoing efforts by CureTB and TBNet to detect, treat and follow-up TB cases in migratory populations.
- CureTB and TBNet should use current political issues as a platform to increase resources. For example, CureTB and TBNet should gather and disseminate data on foreign-born XDR-TB cases to federal, state and local funding agencies. CureTB and TBNet should inform funding agencies that the production of new XDR-TB cases can only be stopped by the completion of TB therapy. Cost-savings generated by TB treatment and care should be strongly emphasized.
- ACET should make a strong statement about the critical need to resume production of the binational TB card in the United States. The TB card has been extremely useful to Mexico and is now being expanded to Guatemala.

Update by ICE

Dr. Diana Schneider, ACET's *ex-officio* representative to DIHS, provided an update on the continuity of TB therapy for ICE detainees. ICE detention is an administrative process to facilitate removal or deportation. Any criminal charges are resolved before admission to ICE custody. ICE must remove detainees within 90 days following the issuance of a final order of removal. A post-order custody review is held if the detainee cannot be deported or other issues prevent ICE from accomplishing the removal within 180 days. ICE cannot hold detainees in custody due to illness. ICE detainees are held in service processing centers, contract detention facilities or local jails throughout the United States.

TB services for ICE detainees include medical and TB screening at intake for infection control purposes, maintenance of a safe detention and working environment, case detection, and continuation or initiation of treatment as indicated. ICE does not deport contagious patients, but detainees with active TB are often deported prior to completion of treatment and before culture results are available. ICE data on detainees with active TB by

country and release status showed that Honduras accounted for 41% of these cases in 2005 followed by Mexico and Guatemala.

ACET made recommendations in 2003 on post-detention completion of TB treatment for persons deported or released from the custody of ICE (formerly the Immigration and Naturalization Service). To implement the recommendations, an interagency workgroup was formed with representation by CDC, DIHS, MCN, the Pan American Health Organization (PAHO), state and local health departments, and other partners with an interest in global TB issues.

ICE established a new process for TB continuity of care following ACET's recommendations. The DIHS Epidemiology Unit is notified about TB cases. ICE requests short-term medical holds until a treatment plan for the detainee is developed and an international or binational referral is made through TBNet or CureTB. ICE staff are encouraged to issue binational TB cards to detainees. A coordinated removal or a medical "meet and greet" is arranged at the point of repatriation between ICE and TB control program staff or public health officials of the receiving country.

ICE also requests stays of removal for exceptional cases, such as detainees with MDR-TB or concomitant mental health conditions, medically complex or non-adherent patients, and detainees who frequently cross the border. However, stays of removal do not ensure continued custody. ICE may require other secure environments because state and local jurisdictions in the United States have authority to compel isolation and treatment.

ICE has faced several challenges in implementing the new process for TB continuity of care. ICE does not always receive advance notification before the detainee's release. Diagnostic and treatment norms in the United States differ from those of other countries. Many detainees are not adherent to TB treatment. Authority to compel isolation and treatment is unclear. The exchange and sharing of information across jurisdictional boundaries is difficult. Case management may become the responsibility of the health department if stays of removal are granted. The Department of Homeland Security has established new initiatives to secure the border, increase detention capacity and expedite removals.

The interagency workgroup made several recommendations in an effort to address these challenges. Foreign national health authorities and the U.S.-Mexico Border Health Commission should be engaged to establish and improve mechanisms that foster binational and international collaborations regarding TB case management. These mechanisms should include electronic sharing of health records and other information, sharing of expertise and resources, availability of treatment and medication, laboratory support, strategies to promote adherence to TB treatment, and enhanced contact investigations.

A public health legal forum should be convened to better facilitate binational and international case management. National TB Programs in foreign countries should be

engaged to promote collaboration with coordinated removal and the TB meet and greet program. CDC should establish a mechanism to count all TB cases that are managed by state and local TB control programs in determining federal funding.

Dr. Schneider concluded her update by describing the interagency workgroup's next steps. ICE will continue its evaluation of the new process for TB continuity of care. ICE will match its data with information collected by CureTB and TBNet to assess outcomes. Interviews will be held with stakeholders as part of the evaluation. Education and outreach will be continued through state and regional TB meetings, a breakout session during the upcoming NTCA meeting, a web-based seminar with the Southeast RTMCC, and educational materials. The interagency workgroup will continue to convene conference calls as needed.

Update by the U.S.-Mexico Border Health Commission (BHC)

Mr. Dan Reyna, ACET's liaison representative to BHC, reported that a 1994 public law facilitated the establishment of BHC in 2000 through an agreement between the United States and Mexico. A Presidential Executive Order designated the BHC as a public international organization in 2004.

BHC operates under its overarching mission, two key objectives and four major roles. International leadership is provided to optimize the health and quality of life along the U.S.-Mexico border. A domestic focus on border health issues that transcends political changes is institutionalized. An effective venue is created for binational discussion to address key public health issues at the border. Identification, study and research are facilitated. Awareness is raised by serving as a catalyst. Sustainable partnerships for action are promoted. An informational portal is provided.

BHC's composition and structure include two nations; six Mexican and four U.S. states; sections in both countries; 24 members representing both countries, including state health officers for the ten Mexican and U.S. states; and commissioners represented by the Secretaries of Health in both countries. BHC's organizational structure also includes standing committees for priority setting and strategic planning; program, planning and evaluation; and budget issues. BHC's workgroups include communication and outreach, bylaws and border health research. BHC has established 13 state outreach offices in both the United States and Mexico.

Mr. Reyna highlighted BHC's key activities. BHC's strategic efforts are focused on *Healthy Border 2010* for community assessment, planning and action on 20 general health indicators in 11 focus areas: access to care, environmental health, oral health, mental health, maternal, infant and child health, cancer, diabetes, respiratory diseases, immunization, infectious diseases, HIV/AIDS, and injury prevention. *Healthy Border 2010* in Mexico was designed to match health indicators established for *Healthy People 2010* in the

United States. BHC and CDC completed a mid-course review on *Healthy Border 2010* in December 2006 that showed indicators for TB, hepatitis B, HIV/AIDS and injury prevention are inappropriate.

BHC has sponsored "Binational Health Week" (BHW) since 2004 to raise awareness about health needs and issues in both the United States and Mexico. The annual theme of BHW is "Families in Action for Health," but BHC's overall goal for this event is to promote sustainable partnerships. Major sessions during the 2006 BHW focused on border health research, TB, health policy and tobacco. Several partners at the 2006 BHW emphasized the need to refocus efforts on TB because the previous "Ten Against TB" initiative has floundered over the past few years. A summary of the TB forum was distributed to ACET for review.

BHC will celebrate "National Infant Immunization/Vaccination Week in the Americas" in April 2007. CDC, PAHO, border agencies and CBOs will partner to coordinate activities along the border to promote immunizations. Border-specific events were launched in 2004 with U.S. border states taking the lead for these activities each year. Texas will serve as the lead state for this event in 2007.

BHC launched a border health research initiative to develop a long-term research agenda. The initial research forum to support this effort was held in Mexico in October 2006. BHC will host additional research forums on a biennial basis in the future. An advisory council will be formed to assist BHC in developing the long-term border health research agenda.

BHC partnered with several organizations to focus on pandemic influenza planning. BHC and the Association of State and Territorial State Health Officers co-hosted a forum on binational public health preparedness in August 2006. BHC hosted a federal-state binational pandemic influenza forum in Mexico in November 2006. BHC collaborated with California to conduct a federal-state binational influenza tabletop workshop in February 2007.

BHC is addressing lead issues along the border in collaboration with a number of groups. U.S. and Mexico federal agencies and border states established a partnership to focus on lead in candy and other non-paint sources. New Mexico led the initial binational discussion on lead issues in January 2006 and California hosted a follow-up binational workshop in September 2006. California is taking the lead in the development of a Binational Lead Workgroup, a Binational Lead Outreach Project, and publication of a binational technical report with lead data from both the United States and Mexico. Efforts will be made to create and launch a health education campaign on lead in Mexican candies and ceramic ware.

BHC and state and academic partners in Mexico and the United States are making progress on a border tele-health initiative to promote the development of a binational network of tele-health linkages. During the planning phase of this initiative, BHC conducted a site visit to the University of Arizona in December 2006 and intends to establish a tri-state

collaborative among academic institutions in Mexico and the United States. Texas Tech Health Science Center has also expressed an interest in becoming involved. The border health tele-health initiative could eventually be designed to improve binational case management of TB cases.

BHC is partnering with CDC and the Mexico Secretary of Health to develop a binational border health information platform. The goal of the web-based database will be to improve capacity to assess and research border health problems. BHC hopes the binational border health information platform will resolve complexities and difficulties in the United States to share data with Mexico. Unlike Mexico, U.S. data are primarily owned by states rather than the federal government. As a result, Mexico is required to establish data sharing agreements and protocols with each individual border state in the United States. Mexico has completed and posted its portion of the electronic database on the BHC web site.

With no further discussion or business brought before ACET, Dr. Fleenor recessed the meeting at 5:40 p.m. on March 20, 2007.

Current ACET Business

Dr. Fleenor reconvened the ACET meeting at 8:36 a.m. on March 21, 2007. He apologized for developing day 1 of the March 2007 agenda with numerous presentations and insufficient time for ACET to discuss and make recommendations on these issues. He committed to adjusting future agendas to allow more time for ACET discussions.

Dr. Fleenor entertained a motion to accept the previous meeting minutes. A motion was properly placed on the floor and seconded by Drs. Burman and Fluck, respectively. ACET **unanimously approved** the draft December 5-6, 2006 Meeting Minutes with no changes or further discussion.

Dr. Fleenor opened the floor for an update and discussion on ACET's previous action items. Dr. Castro reminded ACET that Dr. Fleenor sent a letter to the HHS Secretary in December 2006 regarding the potential for a deadly pandemic of XDR-TB and eroding U.S. capacity for TB elimination. The HHS Secretary asked Dr. Gerberding to directly respond to Dr. Fleenor about this issue. Dr. Castro was pleased about Dr. Gerberding's commitment in the letter to place issues related to TB elimination and the threat of XDR-TB among CDC's leading priorities for FY'08. Dr. Gerberding's March 16, 2007 letter to Dr. Fleenor was distributed to ACET for review.

Dr. Burman expressed concern about Dr. Gerberding's response to ACET. He noted that ACET's letter contained detailed descriptions of several TB issues and suggestions of actions CDC could take to address these issues. However, Dr. Gerberding's letter appeared to be a "blanket" response. Dr. Burman raised the possibility of ACET asking Dr.

Gerberding to specifically respond to each of the issues outlined in the letter rather than issuing a generic statement.

Dr. Castro described options for ACET to consider in addressing Dr. Burman's concern. ACET could request a face-to-face briefing with Dr. Gerberding prior to the next meeting. Participants would include the ACET Chair and a few members. ACET could also invite Dr. Gerberding to attend the July 2007 meeting and report on specific actions CDC would take to prioritize issues related to TB elimination and the threat of XDR-TB in FY'08.

Dr. Fenton agreed with Dr. Castro that Dr. Gerberding should be briefed before the next ACET meeting. The meeting would be timely due to Dr. Gerberding's recent Congressional testimony and current focus on XDR-TB. However, he clarified that most FY'08 activities already have been formulated and the appropriations process for FY'08 priorities has been initiated. NCHHSTP could use CDC's professional judgment initiative as an opportunity to further raise issues related to TB and other infectious diseases.

Drs. Castro, Fenton and Fleenor proposed a process for ACET to meet with Dr. Gerberding prior to the next meeting. Dr. Mitchell Cohen, Director of CCID, would be invited to the meeting due to his responsibility for overseeing the implementation of activities in all CCID centers. Each ACET member would be eligible to attend the meeting, but Drs. Castro, Fenton and Fleenor would determine the optimal size of the ACET subgroup.

Every effort would be made to convene the meeting on the earliest possible date based on the respective schedules of Drs. Gerberding and Cohen. ACET members would immediately submit potential topics to cover during the meeting to Dr. Fleenor. Dr. Fleenor would draft an outline of discussion topics for the meeting based on ACET's agreement of these issues. None of the ACET members expressed opposition to this process.

Dr. Castro informed ACET about recent legislative activities that are relevant to TB. Dr. Gerberding's testimony on this day before the Africa and Global Health Subcommittee of the House Foreign Affairs Committee would be linked to the introduction of the "Stop TB Now" Act. Congressional action was not taken in the past on an earlier version of the legislative proposal, but the current version has a better chance of being passed with Dr. Gerberding's testimony.

Dr. Castro encouraged ACET to continue to follow Congressional activity on the domestic TB legislative proposal to reauthorize the National TB Program with a focus on elimination. If Congress passes the domestic TB legislative proposal, opportunities would most likely be available for additional resources to expand TB program and research activities.

Drs. Castro and Fenton informed ACET that CDC is reemphasizing and clarifying its existing policy for all federal advisory committees (FACs) to provide advice and recommendations to the HHS Secretary. The policy states that communications should flow from the FAC to the CDC Director to the HHS Secretary. However, some FACs have

submitted formal resolutions and recommendations directly to the HHS Secretary without the CDC Director's knowledge of these key issues. Each FAC would still be expected to maintain its independence in providing objective advice to the HHS Secretary.

Dr. Fleenor entertained a motion to address ACET's previous recommendation to invite TAG to serve as a formal liaison member. However, he clarified for the record that ACET is willing to consider and discuss the possibility of inviting other advocacy organizations to serve as liaison members.

A motion was properly placed on the floor and seconded by Drs. Burman and Fluck, respectively. ACET **unanimously approved** TAG as a new liaison member with no further discussion.

Update on the Revised Foreign-Born Guidelines

Dr. Dolly Katz, of DTBE, described ongoing activities to revise the guidelines to control TB in foreign-born persons. This effort was initiated after ACET made a recommendation to revise the guidelines because CDC's 1998 guidelines were outdated. TBESC's study on enhanced surveillance to identify missed opportunities for the prevention of TB in foreign-born persons is nearing completion and will provide important new data to support the revised guidelines.

To assist in revising the guidelines, ACET and DTBE formed a Foreign-Born Workgroup (FBWG) with representation by TB control agencies, clinicians, immigration officials, non-governmental organizations, minority health organizations and patient advocacy groups. FBWG held a meeting in November 2006 and will convene a follow-up meeting on June 13-14, 2007 to report on progress to date.

The focus and purpose of the guidelines are to offer evidence-based guidance and provide practical and useful information. FBWG revised the recommendations section of the guidelines during its November 2006 meeting to focus on nine key areas: a new screening algorithm, critical program elements, special issues for health departments, laboratory issues, special foreign-born populations, non-health department critical partners, policy, education and training resources, and future research needs. The draft outline of the revised guidelines was distributed to ACET for review.

Dr. Katz highlighted issues FBWG is still discussing for three areas of the recommendations section. For the "new screening algorithm," an FBWG subgroup is reviewing data on TB rates among different foreign-born populations in the United States by region of origin and time since arrival. Among foreign-born persons with U.S. residence <2 years, the data dramatically differ from an extremely high rate of 389.2/100,000 from sub-Saharan Africa to an extremely low rate of 1.4/100,000 from Canada.

The subgroup is currently discussing three key issues for the new screening algorithm. Should two different sets of recommendations be made for individual providers and health departments/other institutions? Should risk levels be defined by specific country of origin and time in the United States? What cutoff rates should be established to define "risk?"

For "special issues for health departments," an FBWG subgroup is formulating guidance on program monitoring and evaluation; surveillance and research; completion of treatment; communications with critical partners; and contact investigations, including cross-border migration and higher background rates of infection. The subgroup called for innovative approaches to address these issues by sending a letter to all NTCA members who will attend the June 2007 meeting. The subgroup asked the NTCA members to describe program activities that have been effective in various foreign-born communities. The innovative approaches will be included in the revised foreign-born guidelines.

For "non-health department critical partners," an FBWG subgroup is formulating practical recommendations for various agencies and organizations with a role or interest in screening, treatment, referral or guidance of foreign-born populations. The subgroup developed a table illustrating the potential roles and available tools for each critical partner.

For example, the potential roles of detention facilities would be in the areas of infection control, screening for disease, LTBI testing and cross-jurisdictional care. Available tools for detention facilities would include web-based policy and procedures; existing recommendations for selected TB screening; fact sheets for non-clinician staff; and referral forms and the binational TB card. Descriptions of potential roles and available tools for each critical partner will be included in the revised foreign-born guidelines.

Dr. Katz concluded her update by describing FBWG's next steps. Each subgroup will continue to write its individual sections. A small writing group will be formed to draft introductory sections and perform final editing of the entire document. The revised guidelines will be published as a joint ACET/CDC document. Efforts will be made to submit the document to the CDC clearance process by December 2007. Dr. Katz encouraged ACET to provide her with input on policy issues and future research needs for the two FBWG subgroups to consider.

ACET made two suggestions for FBWG to consider in its ongoing efforts to finalize the revised foreign-born guidelines. FBWG should explore the possibility of using U.S. residence of 2-5/5 years as the cutoff level for risk rather than U.S. residence of <2/$\geq$2 years. FBWG should ensure that the section on laboratory issues includes guidance to public health laboratories on testing algorithms. These recommendations will be particularly important due to the emergence of XDR-TB and new assays that are more expensive than traditional screening methods.

Dr. Castro made several remarks in response to specific questions and comments by Dr. David Mills, ACET's liaison representative to APHL. Public health laboratories will definitely receive additional resources to implement the foreign-born guidelines if new TB funds are appropriated. In the absence of new resources, however, creative strategies will need to be explored. For example, laboratory proficiency and capacity could be maintained by funding regional laboratories to process TB specimens rather than laboratories in each individual state. Dr. Castro encouraged Dr. Mills to contact Dr. Beverly Matchock, of DTBE, to provide additional input on the laboratory section of the revised foreign-born guidelines.

Update on the New Technical Instructions (TIs)

Dr. Drew Posey, of the CDC Division of Global Migration and Quarantine (DGMQ), provided an update on the new TIs overseas panel physicians will use for TB screening and treatment of immigration applicants prior to U.S. arrival. The major changes to the TIs are highlighted as follows. Medical evaluations will be required for applicants $\geq$6 months of age. TST will be required for children 6 months to 5 years of age. Sputum cultures will be required for applicants with abnormal chest radiographs. Panel physicians will still be required to observe and check the quality and accuracy of all sputum specimens collected.

Drug susceptibility testing (DST) will be required for positive cultures. DOT will be required for smear- or culture-positive applicants. The validity period of medical examinations will be reduced to six months if the applicant does not have a TB classification and to three months if the applicant has a Class B1 TB classification. DGMG closely collaborated with DTBE and obtained extensive input from ACET during the process to revise the TIs.

The official version of the new TIs was formally distributed in January 2007 to the International Organization for Migration and the Bureau of Consular Affairs and Bureau of Populations, Refugees and Migration in the Department of State. CDC provided these groups with the new TIs to assist with budgetary planning and initiate implementation. CDC plans to initially implement the new TIs in FY'07 in Mexico, the Philippines, Vietnam, and Thailand for Burmese refugees at Mae La.

Dr. Posey described recent activities that were conducted to prepare the four countries for implementation of the new TIs. CDC made its most recent site visit to Mexico in December 2006. Two panel physician groups in Juarez, Mexico are responsible for screening all immigration applicants. CDC is assisting the groups in building laboratory capacity in the areas of cultures and DST.

The panel physician groups agreed to jointly build a TB laboratory and hired microbiologists from both Mexico and the United States to provide expertise in this area. A process is underway to obtain licensing, accreditation and external quality assurance for the TB laboratory. CDC is discussing available options with experts to improve TB treatment in

Mexico. CDC will make another site visit to Mexico in April 2007 and will also participate in the site visit by the International Organization for Migration laboratory expert in May 2007.

CDC made its most recent site visit to the Philippines in January 2007. The Saint Luke's Medical Center Extension Clinic in the Philippines has a TB laboratory and a DOT program. Efforts are underway to enhance laboratory capacity to implement the new TIs and ensure that MDR-TB therapy is consistent with U.S. standards. Saint Luke's is considering applying to the Green Light Committee for better access to second-line drugs.

CDC and its program review team of ACET and NTCA members will make a site visit to Thailand the week of April 30, 2007 to assess TB screening, laboratory and DOT programs in the country. Thailand is scheduled to begin implementing the new TIs in April 2007 with the screening of Burmese refugees from the Mae La camp.

CDC made its most recent site visit to Vietnam in February 2007. Two panel physician groups in Ho Chi Minh City are responsible for screening all immigration applicants. The groups agreed to jointly build a TB laboratory in Cho Ray, Vietnam. A process is underway to obtain licensing, accreditation and external quality assurance for the TB laboratory. Vietnam already has a DOT program. CDC will make another site visit to Vietnam on March 26, 2007.

CDC is also planning to make site visits to three additional countries to promote further implementation of the new TIs: Jordan, Syria and Turkey in the Middle East; China and Nepal in Asia; and Ethiopia, Kenya and Tanzania in Africa. In the Middle East and Africa, emphasis will be placed on upcoming resettlements of Iraqi, Eritrean, Somali and Burundi refugees.

Dr. Posey reported that in addition to CDC's site visits, DGMQ also took other actions to promote implementation of the new TIs. A manual is being developed to provide technical guidance on the required specifications of the new TIs. To support this effort, DGMQ solicited expertise from DTBE and an intergovernmental workgroup with representation by Australia, Canada and the United Kingdom.

A TB TI Workgroup was formed to facilitate streamlined communication among stakeholders and provide a forum for discussion of the TIs and their implementation. ACET, NTCA, NCET and CDC serve on the workgroup. Drs. Posey and Jennifer Flood, an ACET member, co-chair the workgroup and have started to prioritize and organize comments submitted on the new TIs for future discussion by the entire workgroup. The workgroup convened its first conference call in March 2007 and will hold its second conference call in April 2007.

Several ACET members made suggestions for DGMQ to consider in refining and implementing the new TIs.

- DGMQ should closely collaborate with the Stop TB Workgroup due to its ongoing efforts to establish regional laboratories in foreign countries.
- DTBE should distribute a notice to states with the highest populations of immigrants and refugees from Mexico, the Philippines, Vietnam, and Thailand because these four countries will begin implementing the new TIs in FY'07.
- DGMQ should include a requirement in the TI technical manual for health departments and primary providers of immigrants and refugees who arrive in the United States to establish solid communications. A domestic follow-up strategy would assist in improving poor TB treatment and adherence outcomes after immigrants and refugees arrive in the United States.
- DGMQ should replace the "smear- or culture-positive" language in the new TIs with "positive or negative cultures or smears."

Dr. Castro agreed with ACET's suggestion to communicate with states about the new TIs. He made a commitment to contact the DGMQ Director to discuss the possibility of developing and distributing a joint letter to states to highlight changes in the new TIs and potential expectations at the state level. To assist in this effort, Dr. Castro asked the TB TI Workgroup to draft an outline of key issues that should be covered in the letter. Dr. Fleener encouraged all ACET members to submit additional input to the TB TI Workgroup to ensure that the TIs are as complete and operational as possible.

Resolution of Policy Issues

Dr. Fleenor explained that this item was placed on the agenda for ACET to review and reach resolution on policy issues discussed during previous meetings.

Issue 1. ACET should recommend that DTBE promulgate the latest HIV testing guidelines in healthcare settings for TB patients.

Ms. Suzanne Marks, of DTBE, reported that the latest HIV testing guidelines for healthcare settings recommend routine offering of HIV testing to each TB patient 13-64 years of age who receives care in a clinic. She hoped ACET would pass a formal resolution on this issue because 2006 marked the first year with a decline in reported HIV status among TB patients. If a resolution was passed, she emphasized the need for ACET to support the new opt-out recommendation; describe specific strategies for TB programs to implement this guidance; and promote collaborations between HIV and TB programs throughout the country.

Dr. Fenton added that ACET's resolution would support cross-division initiatives and would also be consistent with NCHHSTP's priorities as additional efforts are made to advance toward program integration. He pointed out that routinization of HIV testing in medical settings is a tremendous driver for CDC at this time. NCHHSTP will identify opportunities to

incorporate HIV funding into TB and STD treatment centers under the new program integration. For example, if new funding is appropriated for HIV testing, a portion of these resources could be allocated to TB clinics to conduct demonstration projects. Similar to Ms. Marks, Dr. Fenton also welcomed ACET's formal support and resolution of this issue.

Comments by the ACET members on issue 1 are outlined below.

- The age limit of 13-64 years for offering HIV testing to TB patients should be changed in the guidelines to "any adult TB patient."
- DTBE should review guidelines on "controlling TB in the United States" that were released in December 2005. The document recommended HIV testing for specific groups of contacts and persons who are screened for LTBI. Language on contacts in the 2005 guidelines and the new HIV testing guidelines should be reconciled to ensure that CDC's policy documents convey consistent messages. A new statement should be included in the new HIV testing guidelines to clarify that opportunities for testing have been expanded rather than restricted.
- DTBE should provide a forum for ACET and the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC) to engage in dialogue on strategic efforts to encourage program integration and synergy between NCHHSTP's TB and HIV/AIDS programs.
- The new HIV testing guidelines should provide an explicit recommendation for TB control programs to re-offer HIV testing or provide rapid HIV testing to TB patients if this technology is available.
- ACET should make a strong recommendation for CDC to allocate additional funding to TB programs to offer routine HIV testing and provide follow-up services, such as partner referrals for positive tests.
- ACET should issue a statement that emphasizes the need to eliminate impediments or barriers to federal, state and local agencies and programs reporting HIV testing data, particularly the Department of Veterans Affairs.
- ACET's resolution should take into account the lack of capacity for TB programs to offer HIV testing at this time due to the impact on and need to conduct contact investigations.

Dr. Fenton made several remarks in response to ACET's comments. He noted that the extensive discussion reflected ACET's strong passion about TB programs offering HIV testing. He also pointed out that CDC is acutely aware of the practicalities of implementing the new HIV testing guidelines in TB programs and other healthcare settings.

Dr. Fenton described options for ACET to consider in strengthening linkages with HIV partners to address these concerns. ACET could use the BSC as a venue for ongoing communications with CHAC because both the ACET and CHAC Chairs serve on this group. ACET could also invite Dr. Bernard Branson, of the NCHHSTP Division of HIV/AIDS Prevention, to a future meeting to discuss concerns and obtain information on models that

have been successfully implemented in promoting HIV testing in the field. Dr. Fenton pointed out that Dr. Branson has been leading the effort to develop and implement the new HIV testing guidelines.

Resolution of Issue 1: The following motion was properly placed on the floor by Dr. Burman, seconded by Dr. Fluck, and **unanimously approved** by ACET.

> ACET endorses routine HIV testing in TB programs using opt-out methodology for persons with documented active TB, TB suspects, and persons identified in TB contact investigations. ACET requests that the Division of Tuberculosis Elimination and the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention [proposed] identify funding to expand HIV testing and evaluate the operational aspects of expanded HIV testing in TB control programs.

Issue 2: ACET should provide formal input on the revised reported verified case of TB (RVCT) document.

Dr. Thomas Navin, of DTBE, was pleased to report that the RVCT revision process DTBE initiated in 2001 was successful. A workgroup of ~30 members who represented 15 TB reporting areas participated in this effort. The revised RVCT document includes new variables, changes to existing variables and new instructions. The document was cleared by DTBE earlier in March 2007 and was distributed to ACET for review and comment.

Dr. Navin conveyed that the most efficient process for DTBE to obtain formal input would be through a small subgroup of a few ACET and NTCA members to coordinate comments. DTBE has a deadline of July 2, 2007 to further revise the document based on input and submit the final revised version to the Office of Management and Budget review process. DTBE is asking ACET to submit comments no later than June 26, 2007.

Resolution of Issue 2: Drs. Narita and Seaworth volunteered to represent ACET on the ACET/NTCA subgroup to coordinate ACET's comments on the revised RVCT document.

Issue 3: ACET should take actions to formally and strategically address the TB disparity in U.S-born AAs and other racial/ethnic groups.

Mr. Shannon Jones III, an ACET member, cited data to demonstrate the importance of addressing and prioritizing the TB disparity in U.S-born AAs and other racial/ethnic groups. CDC's strategic plan to address, analyze and monitor the burden of TB in foreign-born populations is not as clear or comprehensive as its activities for U.S.-born AAs. U.S.-born AAs have a disproportionate share of TB in the United States. The TB case rate of 10.8/100,000 among U.S.-born AAs was >8 times higher than the rate of 1.3/100,000 among U.S.-born whites in 2005. AAs accounted for 45% of all TB cases reported among U.S.-born persons in 2005.

Mr. Jones pointed out these data demonstrate the lack of success of traditional approaches and strategies in addressing the TB disparity in the AA community. In an effort to make progress on this issue, he proposed three activities for an ACET vote. ACET should establish a new "TB in AAs Workgroup." ACET should invite the National Medical Association (NMA) to serve as a formal liaison representative and a member of the new workgroup. ACET should recommend that CDC assign a staff member to coordinate activities of the new workgroup.

Mr. Jones explained that based on ACET's approval, the new workgroup will be established with the following charge. Strategies will be explored to reconfigure funding algorithms and allocate resources to SE-8, Florida and Texas. These states have the highest TB burden among AAs that is proportionate to population TB case rates.

Linkages will be formed with external partners to foster ongoing communication and further address the TB disparity in AAs. External guidance will be offered to CDC in the development of guidelines that govern the practice of TB services for AA populations. Mr. Jones concluded that activities conducted by the new workgroup would serve as an initial step in developing a strategic plan on the elimination of the TB burden in the AA population.

Dr. Castro made an announcement in response to the proposed activity to invite NMA to serve as a formal liaison representative on ACET. CDC previously sent a letter to NMA with this request, but NMA did not respond. During a follow-up telephone call, CDC was informed that NMA would discuss the invitation with its board and notify CDC about its decision before the next ACET meeting. Dr. Castro encouraged any ACET member with a relationship to NMA to contact NMA and emphasize the importance of its representation on ACET.

Several ACET members and CDC representatives made comments on the proposed activity for ACET to establish a new TB in AAs Workgroup with the charge as outlined by Mr. Jones.

- The workgroup should not limit its focus to SE-8, Florida and Texas because many non-Southeastern cities and major metropolitan areas also have a large burden of TB cases among AAs.
- The workgroup should review lessons learned and experiences of the HIV and syphilis models in addressing health disparities among AA populations.
- The workgroup should consider two key issues while formulating guidance on resources. The recommendations should reflect CDC's funding mechanisms to allocate dollars to states directly and some large cities. The language should also clarify that any additional funds allocated to TB programs for this effort would be dedicated to specific activities on the TB disparity in AAs rather than general TB activities.

- The workgroup should expand the proposed charge to take a more holistic and integrated approach and address the broader area of "infectious disease" disparities in the AA community, including TB, HIV and STDs. This goal could be achieved by the workgroup linking with "partners" rather than "external partners" only.
- The workgroup should explore the possibility of coordinating with other CDC centers to expand its focus to include chronic disease disparities in the AA community, particularly diabetes.
- The workgroup and CDC should develop guidelines that describe the evidence base for interventions with success in decreasing TB in AA populations.

Resolution of Issue 3: A motion for CDC to take the necessary steps for NMA to serve as a formal liaison representative on ACET was properly placed on the floor by Mr. Jones, seconded by Mr. Kinney, and **withdrawn** based on Dr. Castro's announcement. Dr. Castro confirmed that he would distribute a copy of CDC's letter to NMA to Dr. Litjen Tan, ACET's liaison representative to the American Medical Association.

The following motion was properly placed on the floor by Mr. Jones, seconded by Mr. Kinney, and **unanimously approved** by ACET.

> ACET will establish a new TB in AAs Workgroup with an amended charge. The workgroup will form linkages with partners to foster ongoing communication and further address the TB disparity in AAs. The workgroup will offer external guidance to CDC in developing evidence-based guidelines that govern the practice of TB services for AA populations.

Dr. Fleenor outlined procedural issues related to the establishment of the new workgroup. As the ACET Chair, Dr. Fleenor would serve on the workgroup to facilitate communications among the workgroup, ACET, the BSC, CHAC and other relevant groups. Mr. Jones will serve as the acting chair of the new workgroup, but a permanent chair would be appointed during the workgroup's first conference call.

Dr. Fleenor clarified that ACET would not need to make a formal motion on the proposed activity for CDC to assign a staff member to coordinate activities. CDC's routine practice is to designate staff members to participate on, serve as points of contact, and provide logistical and other types of support to workgroups.

Issue 4. ACET should make recommendations to the HHS Secretary on specific initiatives along the U.S.-Mexico border, broader trans-border activities, and coordination of these efforts with USAID.

Ms. Garcia reminded ACET that both TBNet and CureTB described their severe budget cuts during presentations on the previous day. TBNet has lost its external funding source

and CureTB is facing dramatic reductions from state and cooperative agreement dollars. Ms. Garcia encouraged ACET to issue a strong statement on the need for immediate funding if these projects are considered to have merit and value in creating a trans-border infrastructure.

Dr. Schneider described other issues that ACET should consider if agreement was reached to make a formal resolution on trans-border activities. CDC should establish a mechanism to count all TB cases managed by state and local TB control programs in determining federal funding. This system should extend beyond U.S.-Mexico binational cases to include cases from any country in the world that are managed by U.S. TB control programs and place a burden on state and local health departments in the United States.

An infrastructure with adequate financial and personnel resources should be supported for the transport and transmission of multinational TB cases across borders. An electronic, secure and web-based data system should be developed to facilitate sharing of information across borders. CDC should expand language on "binational" cases in its revised RVCT document to include "trans-border" or "global" cases that are co-managed in the United States.

The ACET members made two key comments related to issue 4. First, language on electronic data systems in ACET's resolution should not be limited to CDC. Linkages should be made to ongoing efforts at international and other federal levels to create web-based health records. DTBE should explore the possibility of expanding CDC's electronic data system that is being implemented in 2007-2008 to notify states of overseas TB evaluations. Second, ACET's resolution should specifically state the minimum dollar amount that would be needed each year to sustain CureTB and TBNet.

Resolution of Issue 4: The following motion was properly placed on the floor by Dr. Fluck, seconded by Dr. Burman, and **unanimously approved** by ACET.

> ACET requests emergency funding to continue trans-border case management activities of CureTB and TBNet to maintain TB continuity of care for mobile populations. ACET requests maintenance and enhancement of the necessary activities and infrastructure for trans-border TB case management, including but not limited to (1) a TB health card using the U.S.-Mexico binational TB card as a model; (2) electronic health records and other innovative strategies to facilitate information sharing across jurisdictional boundaries and healthcare systems; and (3) staffing and resources. ACET requests the development of a mechanism to account for all trans-border TB cases managed in the United States for determination of federal funding regardless of nationality.

Issue 5: ACET should make a recommendation to the HHS Secretary to advise the Centers for Medicare and Medicaid Services (CMS) to consider developing a pay-for-performance indicator for TB services.

Comments by the ACET members on issue 5 are outlined below.

- ACET should attempt to incorporate TB into CMS's demonstration projects on pay-for-performance indicators for diabetes and hypertension because these conditions affect the same populations.
- ACET should advise CDC to perform a thorough literature review on the impact of co-payments on the control of TB, STDs and other transmissible infections. Data from the literature review could be used to facilitate the development of national guidelines and support ACET's formal recommendation on the role of co-payments in disease control programs for transmissible infections.
- ACET's recommendation should be expanded beyond co-payments to address the broader shift among federal agencies toward a new model of managed care practices.
- ACET should invite representatives from the five states that have successfully implemented the Medicaid TB option to present these models at a future meeting.

Dr. Castro described additional options for ACET to consider to advance the proposed resolution. CDC could use an upcoming FTBTF meeting or conference call as an opportunity to initiate dialogue with CMS about the development of a pay-for-performance indicator for TB services. ACET could invite a CMS representative to a future meeting to make a presentation on the process of developing pay-for-performance indicators.

Resolution of Issue 5: The following motion was properly placed on the floor by Dr. Burman, seconded by Dr. Flood, and **unanimously approved** by ACET.

> ACET recommends that CDC evaluate co-payments and other patient-centered financial burdens in the control of TB, STDs and other infectious diseases.

Issue 6: ACET should provide formal input on the White House's plans to convene an interagency team to address XDR-TB.

Resolution of Issue 6: The following motion was properly placed on the floor by Dr. Fleenor, seconded by Dr. Burman, and **unanimously approved** by ACET to adopt option 1 as its formal resolution on the White House XDR-TB interagency team. ACET adopted option 1 under the condition that Dr. Castro would revise the "senior-level interagency" language for consistency with the original wording used in Congressional testimony.

Option 1: Be it resolved that the Advisory Council for the Elimination of Tuberculosis (ACET) strongly recommends convening a senior-level interagency meeting to formulate a comprehensive response and to assign responsibilities for a unified U.S. government strategic approach to address the critical health threat of XDR-TB. The senior-level interagency group shall include a member who will represent ACET; a member who will represent the National Tuberculosis Controllers Association; and technical advice from an employee designated by the Director of the CDC Division of Tuberculosis Elimination.

Option 2: Be it resolved that the Advisory Council for the Elimination of Tuberculosis (ACET) strongly recommends convening a senior-level interagency meeting to formulate a comprehensive response and to assign responsibilities for a unified U.S. government strategic approach to address XDR-TB. The senior-level interagency group shall include a member who will represent ACET and a member who will represent the National Tuberculosis Controllers Association. In addition, ACET strongly recommends that the senior-level interagency group seek assistance from the CDC Division of Tuberculosis Elimination.

Dr. Castro encouraged the ACET members to nominate themselves or other appropriate persons to participate in activities of the senior-level interagency group.

Panel Presentation on World TB Day

ACET's agenda was extended to allow for a special panel presentation in observance of World TB Day.

Dr. William Mac Kenzie, of CDC, reported on current global TB control efforts. From 1990-2005, primary factors in the dramatic increase in the global TB incidence were HIV in Africa and MDR-TB in the former Soviet Union. HIV and MDR-TB have led to the Stop TB Partnership updating its "2006-2015 Global Plan to Stop TB." The new global plan builds on the 2001-2005 global plan that was primarily based on DOT short-course (DOTS).

The new global plan outlines priorities and activities to address TB/HIV co-infection and MDR-TB with clear targets. The global plan also represents an important next step in eliminating TB by 2050. WHO's existing DOTS strategy is relatively unchanged in the new global plan, but two key revisions were made. A global commitment will be made to both TB and HIV control. A shift will be made from microscopy-based case identification to culture and drug sensitivity-based identification and testing.

The new global plan was developed with the following components. DOTS expansion and enhancement will be continued to improve case finding. TB/HIV co-infection and MDR-TB will be addressed by promoting HIV testing of all TB patients and screening of all persons living with HIV/AIDS (PLWHA). Diagnosis and treatment of MDR-TB will be strengthened through increased culture and drug sensitivity testing and DOTS-plus programs. Health systems will be enhanced.

Human and financial resources will be mobilized. All care partners and providers will be engaged through the establishment of "International Standards for TB Care." Partnerships for TB care will be enhanced within and between public agencies and private organizations. All persons with TB and affected communities will be involved in social mobilization efforts. Research will be enabled and promoted to develop new drugs, diagnostics and vaccines.

Dr. Mac Kenzie described the most significant challenges in implementing two areas of the new global plan. For TB/HIV co-infection, sub-Saharan Africa accounts for a major part of the global burden with 38% of all TB cases in Africa estimated to have had HIV in 2004. At this time, 41 countries have TB/HIV co-epidemics. Of 32 countries with an existing TB/HIV infrastructure, 23 have a national TB/HIV manager; 20 have intensified TB case finding policies for PLWHA; 18 have universal testing policies for TB patients; 21 have policies to provide antiretroviral therapy to TB patients; and 17 have TB/HIV referral systems.

A goal was established to test 600,000 TB patients for HIV worldwide in 2006, but the goal was reached in only 125,000 patients. Another goal was established to place 200,000 TB/HIV co-infected patients on antiretroviral therapy in Africa in 2006, but the goal was reached in only 15,000 patients. WHO and its partners are continuing to make diligent efforts to develop basic policy guidelines, training protocols and an infrastructure to address TB/HIV co-infection worldwide.

For MDR-TB, country data were reviewed in 2004 to estimate the global burden. Of 425,000 MDR-TB cases estimated worldwide, China and other parts of the Western Pacific Region accounted for 152,000 cases; India and other parts of Southeast Asia accounted for 115,000 cases; Russia and other parts of EURO accounted for 14% of cases; and Africa accounted for 2.2% of cases. However, the estimate from Africa on MDR-TB cases is believed to be an underestimate.

MDR-TB rates among previously treated cases were >40% in the former Soviet Union and 20%-40% in Mexico. Country data showed that China also had high MDR-TB rates among previously treated cases. A similar trend in MDR-TB rates was observed in new cases as well. In addition to rates, country data showed that India and China had the highest number of individual MDR-TB cases.

The review of country data illustrated two major barriers to addressing global MDR-TB. First, limited drug sensitivity testing for second-line drugs accounts for underestimations of MDR-TB cases worldwide. Second, country data are severely flawed. Most notably, the

majority of countries in Africa have no systematically selected data regarding drug sensitivity testing. China, India, Russia and other countries with a high burden of MDR-TB typically collect sub-optimal national data. Mexico's most recent MDR-TB data are from ten years ago.

Dr. Mac Kenzie emphasized that XDR-TB presents an additional challenge to implementing the new global plan. Second-line drugs were previously introduced worldwide to low- and mid-income countries to address MDR-TB, but many of these countries had a high TB burden and HIV prevalence. These factors led to overburdened public health systems and programs, sub-optimal TB control practices, high default rates, inadequate DOT and drug supply issues.

WHO developed a new plan with several components to address the emergence of XDR-TB. Basic TB and HIV/AIDS control will be strengthened. Programmatic management of MDR-TB will be scaled-up to reach global plan targets. Laboratory services will be enhanced to facilitate adequate and timely diagnosis of MDR-/XDR-TB. Surveillance will be expanded to understand the magnitude and trends of XDR-TB. Linkages between MDR-/XDR-TB will be investigated.

Solid infection control measures will be fostered to reduce transmission. Advocacy, communication and social mobilization will be increased. Efforts will be made to pursue new resources at country, regional and global levels. Additional research will be performed to develop new drugs, diagnostics and vaccines.

Dr. Eric Pevzner, of CDC, presented data on recent trends in TB incidence in the United States that would be published in the *MMWR* after the embargo was lifted on March 22, 2007. Based on national data, the TB incidence rate decreased by 3.2% from 4.8/100,000 in 2005 to 4.6/100,000 in 2006. However, a statistical methodology demonstrated that the national decline in the TB rate has slowed over time from an annual percent change of 7.3% in 2000 to 3.8% in 2006. Based on state data, TB case rates ranged from 0.8/100,000 to 12.6/100,000.

Based on sub-group data, the number of TB cases among U.S-born persons has dramatically declined since 1993. However, the number of cases among foreign-born persons has remained relatively stable over this time period with an increase in 2006. The TB rate has decreased over time between 1993-2006. Since 2005, U.S.-born TB cases have declined by 7% with a current rate of 2.3/100,000. The TB case rate among foreign-born persons was 21.9/100,000 in 2006. The foreign-born to U.S.-born ratio has increased 7% from 8.9/100,000 to 9.5/100,000.

Based on racial/ethnic data, the percent change in the rate and number of TB cases declined between 2005 and 2006. However, TB disparities have continued to persist among different racial/ethnic groups. Among foreign-born persons in the United States in

2006, Asians accounted for a TB rate of 25.6/100,000 and Hispanics accounted for a TB rate of 9.2/100,000.

Based on TB/HIV co-infection data, 68.3% of 10,986 TB cases reported in the United States in 2006 knew their HIV status and 31.7% had an unknown HIV status. The 2,781 TB cases that California reported in 2006 were excluded from these data due to the state policy of only reporting HIV-positive data and its one-year delay in reporting HIV data. Of 932 TB cases with reported HIV status, 12.4% were positive and 87.6% were negative. TB cases with unknown HIV status increased by 10.3% from 28.7% in 2005 to 31.7% in 2006. TB cases with positive HIV status decreased by 4.4% from 13% in 2005 to 12.4% in 2006.

Based on MDR-TB data, 1.2% of all TB cases are MDR-TB. This proportion has remained constant between 2004 and 2005. U.S.-born MDR-TB cases decreased from 24% in 2004 to 17.7% in 2005, while foreign-born MDR-TB cases increased from 76% in 2004 to 81.5% in 2005.

Dr. Pevzner summarized key outcomes from the data on recent trends in TB incidence. The TB rate continues to decline. However, the slower rate of decline threatens the TB elimination goal. Foreign-born and racial/ethnic minorities continue to be disproportionately impacted by TB. The HIV status is unknown for nearly 33% of TB cases. The proportion of TB cases that are MDR-TB remains constant.

Mr. Victor Tomlinson, of CDC, provided additional details about the first "TB Awareness Walk" that would be held on March 24, 2007 in Grant Park in Atlanta, Georgia. At this time, 550 persons have registered for the event and Dr. Gerberding has encouraged her immediate staff to participate in the walk. The walk would begin at 9:00 a.m. and would cover ~2 miles. CDC, its partners and sponsors began making preparations for the walk in April 2006. These groups include NTCA, ALA, the Fulton County Health Department, Georgia Division of Public Health, Watsonian Society, RESULTS International, and local businesses.

The planning committee used a variety of venues to notify the public about the event, including letters to ~400 churches; mass e-mail communications; listservs and databases; web sites of the media, professional organizations, academic institutions and public health partners; notices in a Spanish-speaking newspaper and other community publications; internal announcements to all CDC employees; and a personal appearance on a local radio program. TB Awareness Walk business cards, brochures, handouts and flyers were developed and disseminated as well.

The walk will be launched with opening remarks by Drs. Gerberding and Fenton, Ms. Pozsik, and a representative of an advocacy organization, RESULTS International. Mr. Tomlinson thanked the planning committee members, partners, sponsors and volunteers for providing T-shirts, bottled water and fruit and making other contributions for the event. He

hoped that other agencies and organizations would replicate the walk in other areas throughout the country.

In observance of World TB Day, Dr. Castro thanked ACET for continuing to provide CDC and HHS with objective advice and expertise on eliminating TB as a public health problem in the United States. ACET applauded DTBE for its tremendous, diligent and long-standing efforts to achieve the TB elimination goal. The ACET members expressed their appreciation for the opportunity to celebrate World TB Day with DTBE.

New ACET Business

Drs. Burman and Schneider informed ACET that the Office of Human Research Protection (OHRP) is proposing guidance to define several activities as "research," including reporting of surveillance data, other data collection activities, performance improvement and evaluation. CDC and other groups expressed concern that the proposed guidance could serve as a tremendous barrier to program evaluation efforts. In response to these concerns, OHRP will soon release a revised guidance document for public comment.

Dr. Burman was in favor of ACET releasing a formal statement to express its position on this issue. Due to the importance of prompt reporting of surveillance activities in TB control and other efforts, the guidance might have serious implications on the ability to use surveillance data. If ACET decides to develop and release a formal position statement, Dr. Burman offered to assist in this effort.

Dr. Castro supported the suggestion for ACET to draft and send a position statement or letter to OHRP with its views on surveillance and program evaluation. He described two key issues that should be covered in the statement. ACET should emphasize the need to maintain these issues as public health practice activities. ACET should point out that characterizing these activities as research would impair capacity to perform surveillance and program evaluation in a timely manner. Because the revised guidance is expected to be released for public comment before the next ACET meeting, Dr. Castro suggested that ACET convene a conference call to further discuss drafting a position statement or letter to OHRP.

The action items and agenda items raised over the course of the meeting are outlined below for the record.

Action Items

- Ms. Margie Scott-Cseh, ACET's Committee Management Specialist, will provide ACET with CDC's written policy for FACs to communicate with the HHS Secretary.

- Dr. Castro will provide ACET with OHRP's proposed guidance document on research for review and comment within the next week. Ms. Scott-Cseh will make logistical arrangements for ACET and DTBE to discuss next steps during a conference call.
- DTBE will explore the possibility of providing ACET with CD-ROMs rather than paper copies of meeting materials.
- Dr. Fleenor and DTBE will continue to make efforts on improving future agendas. The number of presentations will be fewer and shorter to provide ACET with more discussion time. CDC staff who are scheduled to present ten-minute updates will be reminded to limit the number of slides.

Agenda Items

- Update on RTMCC activities, including web-based medical consultations and evaluation results of RTMCCs by TB control programs.
- Update on rapid TB diagnostic testing and genotyping.
- Presentation on TB deaths from a national perspective.
- Presentation on outcomes of TB treatment failures and relapses.
- Presentation on TB education for health professionals across different disciplines by the National Tuberculosis Curriculum Consortium as the grantee for this initiative and the National Heart, Lung and Blood Institute as the funding agency.
- Presentation by Colorado, Mississippi and North Carolina on state health regulations that require DOT treatment of respiratory tract TB cases.
- Discussion on existing public health laws, resources, unmet needs and strategies to increase political will to properly conduct TB control, oversight and monitoring in the United States.

Public Comment Period

Dr. Fleenor opened the floor for public comments; no participants responded.

Closing Session

The next two ACET meetings will be held on July 10-11, 2007 and October 16-17, 2007.

With no further discussion or business brought before ACET, Dr. Fleenor adjourned the meeting at 2:30 p.m. on March 21, 2007.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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Michael E. Fleenor, M.D., M.P.H.
Chair, Advisory Council for the
Elimination of Tuberculosis